

FINAL REPORT

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CONTRACTOR: Georgetown University Medical Center
3800 Reservoir Rd
Washington, DC 20007

Primary Investigator: Seong K. Mun, Ph.D.

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1 Executive Summary

Patients with end stage renal disease undergo kidney dialysis while waiting for a kidney transplant surgery, often for several years. Hemodialysis is performed at designated out-patient settings where the patients come several times a week. Each hemodialysis session lasts around 4 to 4 1/2 hours . However, some patients either do not show up at the clinic for their dialysis session or attempt to leave the clinic before the full amount of dialysis is delivered. This type of behavior will make the patient sick. Dialysis clinics are usually staffed by nurses and the physicians visit the patients at the center in at regular intervals, depending on the rules of the locality.

In evaluating the role of telemedicine in a dialysis center, it was hypothesized that increasing the quality and quantity of interaction between the physicians and patients and providing more comprehensive patient data to the physicians, telemedicine can improve the patient outcome and eventually reduce the cost of care. The clinical outcome of the dialysis service is directly linked to the amount of dialysis each patient receives which is represented by numerical values of Kt/V. By tracking the changes in Kt/V, one can easily assess patient outcome. A telemedicine network based on PC-based interactive video was established by linking a dialysis center, a physician's office and a physician's home over a dedicated T-1 line.

We setup a controlled study where data were collected from two patient groups —one receiving conventional care, the other conventional care supplemented by telemedicine interventions. These data included Kt/V results, validated quality of life (QoL) measurements and patient satisfaction survey findings, all of which were collected and/or administered regularly to gain insight into the effect of telemedicine interventions on hemodialysis patients. Analyzing the average Kt/V levels between the 2 groups showed that the patients receiving standard treatments exhibited higher levels of Kt/V; however, these results were not statistically or substantially significant. A multivariate analysis was used to explain the difference, and it showed the average Kt/V levels for the telemedicine patients were not significantly different than those for the standard dialysis patients. The correlations between the Kt/V and QoL were low but they were in the anticipated direction (although they were not statistically significant). Comorbidity's effect on the QoL behaved as expected, with most coefficients being in the anticipated direction, some of these statistically significant. As for our patient satisfaction data, we found that patients

tended to be satisfied with their medical treatment, with no significant differences in satisfaction between the two groups.

Our communications analysis suggests that although patients perceive a telemedicine interaction as different from an in-person interaction, this perception did not influence the topics they discussed with their physician. Also, while the physicians perceived that the telemedicine session took was of longer duration than conventional clinic visits, our analysis showed that in-person rounds took longer than telemedicine ones.

For our cost analysis, a slightly significant effect in the hypothesized direction was seen for outpatient visits, while for all other measures the findings were not statistically significant. Post hoc analysis of statistical power was performed to explain this conclusion, and it was found that power approached the acceptable range for outpatient visits only. For the other variables power was too low to confidently state that if a difference truly existed it would have been detected.

Project Phoenix posed the question: What constitutes the “organizational dimension” of assuring the security of health information, particularly but not only patient information? We easily recognized certain organizationally related tasks such as sponsoring training for staff or revising policies in response to new federal, state or professional regulations. We also recognized that many of these tasks clearly fall under the responsibility of professional staff dedicated to managing medical records or information technology. We came to recognize, however, that managing the “organizational dimension” of health information security requires assuring the security and confidentiality of medical information becomes incorporated into the every day working routines of all members of the organization, including patients, vendors, business partners, individual staff, the data security team and an organization’s general administration. When this condition occurs, we say that a healthcare organization has become “security-capable”. We identified three general steps in an ongoing security surveillance process necessary for this to occur, including:

1. Monitoring the changing legal and regulatory environment
2. Continuously updating data security policies, procedures and practices in light of changing mission and
3. Enhancing patient understanding of the organization’s data security efforts

Creating a security-capable organization will enhance management of a paper or computer-based record system. When an organization institutionalizes this process, nonetheless, it creates conditions for allowing the computer-based patient record to provide better access, integrity and confidentiality than paper records in health care while enhancing patients' trust in its overall business operation.

An Internet based educational tool, HelpBot, was developed to help address the question of data security and patient privacy. The patients saw HelpBot as useful educational material to understand the complexity of data security. It was concluded that data security and patient privacy cannot be achieved through technological means alone. It can be achieved only through a comprehensive approach of building a security and privacy conscientious organization through technology, education, policy and procedures. The security and confidentiality work of Project Phoenix became an important basis for participating in other security related projects such as the Health Information Protection and Privacy Act (HIPPA).

2 Introduction and Significance

2.1 Introduction

Project Phoenix was undertaken to evaluate the role of telemedicine in improving access of physicians to patient data and of the patient to their physician improves the quality of healthcare while lowering the cost. We identified the following limitations in the traditional paper-based renal dialysis service:

- a. Patient access to the physician is limited
- b. Physician access to the patient data and patient is limited
- c. Data necessary to manage the patients are widely dispersed
- d. Remote real-time acquisition and transmission of relevant data is not possible
- e. Physician is unable to reassure patients threatening to shorten their prescribed dialysis time

Project Phoenix addressed these issues with the development of a Renal Dialysis Patient Management (RDPM) service that electronically linked one primary outpatient care facility, a nephrologist's home, and the nephrologist's office.

In this environment, we looked at the impact of telemedicine on the process of care for the patients who were in the renal dialysis service. We investigated telemedicine's effect on outcomes of care including Kt/V, survival, hospitalization, and other indications of morbidity. We looked at the quality of life of the patients and their overall satisfaction with life, care and telemedicine, and undertook a cost evaluation using self-reported utilization data that were reported by patients each week.

The results of these analyses as well as details of our investigations into privacy and confidentiality matters in the electronic environment are provided in this final report.

2.2 Significance

Patients with uremia or End-Stage Renal Disease (ESRD) retain in their bodies excessive amounts of breakdown products of protein metabolism, such as urea and creatinine as well as other solutes such as sodium and potassium. They lose the ability to excrete water and lose essential hormones produced in the kidney. In order to eliminate these breakdown products and solutes, ESRD patients undergo hemodialysis, a mechanical process whereby blood is removed from a patient's body, cleansed of unwanted impurities and returned to it. Hemodialysis is the major form of renal replacement therapy for patients with ESRD and carries in the US a 22% first year gross unadjusted mortality, a figure which greatly exceeds that of Europe (14%) or Japan (12-14%). Several studies have suggested that the higher annual mortality rate for hemodialysis patients in the United States compared with those in Europe and Japan is due to decreased dialysis time and inadequate dialysis dose.

The Kt/V_{urea} Ratio and Serum Albumin in End-Stage Renal Disease

One of the main surrogate markers of the quality of clinical services for individual patients undergoing dialysis is the Kt/V_{urea} (written as Kt/V for the remainder of this report) ratio-a global standard for the measurement of the quantity of dialysis delivered. Kt/V, a dimensionless number relating dialysis urea clearance (K), time on dialysis (t), and the volume of the urea pool (V - or whole body water), is significantly tied to patient survival and morbidity. The higher the value of a patient's Kt/V ratio, the better the outcome and the lower the cost of treatment regardless of the primary reason for ESRD necessitating dialysis. Studies have shown an

increased relative risk of death for Kt/V values of less than 1.2. As will be described below, Kt/V ratio and serum albumin levels directly affect the cost of medical care of kidney dialysis patients, including hospitalization.

ESRD and Medicare Costs

Medicare reimburses the cost of care of ESRD to a total cost of \$8 billion per year. There are over 150,000 patients on dialysis or receiving transplants from the Medicare ESRD program. Hemodialysis costs on average \$30,000 per year per patient. Cost varies depending on the intensity, length and frequency of the adverse medical events leading to hospitalization. As shown in the USRDS study, in-hospital day rates per patient year at risk are 15.8 days per year.

Therefore we hypothesized that by improving the Kt/V by using the RDPM telemedicine system would:

- a. reduce the frequency of medical events,
- b. improve the patient's quality of life
- c. improve the patient's satisfaction with life, care, and telemedicine
- d. reduce costs to patients and the health care system.

We felt that by providing telemedicine consults to the patients while on hemodialysis, we could encourage them to stay on their dialysis throughout their session and therefore improve their Kt/V.

3 Key Contributors to the Final Report

There have been many changes in personnel over the life of the Project Phoenix Contract. Seong K. Mun, PhD has been the Principal Investigator for the entirety of the contract. He has been responsible for guaranteeing that the project is on-track and moves forward as specified in the contract. Betty A. Levine, MS has been a very skilled and effective program manager and was responsible for overseeing the daily operations of the project, coordinating the different sections and teams, and handling any issues or concerns that arose on a daily basis. James Winchester, MD was the clinical director. His responsibilities included managing clinical operations, ensuring that the clinical aspects of the dialysis treatment were not compromised due to telemedicine, but were enhanced. Dr. Winchester provided a good deal of important feedback related to the operations of a dialysis center and treatment of the patients. Jeff Collmann, PhD

acted as the security and ethics team leader. A major portion of Project Phoenix was to look at the issues of privacy, confidentiality, and ethics as these concerns may be affected by telemedicine. Our three main contributors to the evaluation section include Alan Neustadt, PhD, of the University of Maryland, Jeanine Turner, PhD, of the Georgetown University School of Business, and James Grigsby, PhD of the University of Colorado in Denver. They were responsible for the clinical analysis, patient-physician interactions, and cost evaluations, respectively.

4 Operational Environment

4.1 Dialysis Sites

Two dialysis sites were identified in Phase One of Project Phoenix to establish the infrastructure for a comparison study between patients on hemodialysis receiving conventional (or non-telemedical) services and patients receiving services via telemedicine in addition to face-to-face consults. Total Renal Care, Inc. (TRC) at Union Plaza in Washington, DC was established as the dialysis telemedicine site. The dialysis center at Georgetown University Medical Center (GUMC) was established as the control site for non-telemedicine sessions. TRC is a renal dialysis management company that operates the unit at Union Plaza with GUMC. During Phase 2 of the Project, GUMC opened the Georgetown-on-the-Potomac off-campus dialysis center in collaboration with TRC on K Street in Washington, DC. All non-telemedicine dialysis patients who had been seen at the GUMC site were now seen at this new location.

A telemedicine network was established linking TRC Union Plaza, the office of the project's nephrologist, Dr. James Winchester, and Dr. Winchester's home, using T-1 lines provided by Bell Atlantic. By January 1997, three PC based desktop telemedicine units were installed at all 3 sites participating in the project. Appendix 1 contains a diagram of the configuration of our telemedicine network. By April 1997, the Union Plaza site was fully operational, and could accommodate 3 shifts of hemodialysis patients per week. Telemedicine sessions were routinely held between the TRC Union Plaza dialysis center and at either Dr. Winchester's home office or office at GUMC.

4.2 Patient Population

Final patient enrollment at both sites was 35 in the control group and 43 in the telemedicine group. Recruitment of patients for the project was initiated at the outset and continued for approximately 2 years. We ensured that all enrolled patients completed an informed consent form.

Once enrolled, patients began participating in the project either as telemedicine subjects or as members of the control group based on the location of their hemodialysis. All patients enrolled at TRC Union Plaza were telemedicine patients and those at Georgetown-on-the-Potomac comprised the control group. We chose to treat the sites as telemedicine or non-telemedicine sites. In the Evaluation and Analysis section of this report we describe in detail the demographic characteristics of the patient populations and their differences.

4.3 Clinical Operations Protocol

With the introduction of the RDPM system to the Renal Dialysis Service, operations protocols were designed to handle the following two scenarios:

- 1) The nephrologist is NOT at the telemedicine site and performs telemedicine rounds or crisis interventions from his office or home.
- 2) The nephrologist is at the telemedicine site performing rounds and utilizes the telemedicine system as a multimedia database.

Routine telemedicine consultations with the nephrologist were performed weekly in addition to the traditional in-person round that was required on a weekly basis by District of Columbia regulations. The nephrologist and nurse worked together to develop a schedule for the telemedicine rounds every week for each shift of patients. The nephrologist was asked to complete a consultation timesheet marking the beginning and ending of each consultation. The nurse was responsible for initiating the telemedicine consultation and setting up the equipment.

One important role of telemedicine was to assist in responding to the following crisis situations:

- A patient deciding to stop their dialysis early
- A patient having trouble with vascular access

- Other problems/complications (dyspnea, tachycardia, pyrexia, bleeding, etc.) that the nurse may deem necessary to call the nephrologist for assistance.

These situations could occur while the nephrologist was performing a routine telemedicine consult with that patient; while the nephrologist was performing a routine telemedicine consult with another patient; while the nephrologist was away from TRC Union Plaza and not performing a telemedicine consult; or the nephrologist was physically present at Union Plaza. The protocol for handling these situations is included in Appendix 2.

While performing the telemedicine consult, the nephrologist had access to the patient folder that was created for each patient seen via telemedicine. Data within the folders and thus available to the nephrologist during routine and non-routine telemedicine consultations included:

- An electronic still image capture of the patient's fistula
- An electronic audio file of the patient's cardiac status
- Scanned medical history, lab values, EKGs, and X-ray reports
- Scanned Progress Notes and Physician's Orders. These forms were always updated during regular telemedicine rounds

5 Evaluation and Analysis

5.1 Clinical Evaluation of Telemedicine and ESRD

Kt/V Levels, Satisfaction Analyses, and Quality of Life Analysis

Validated questionnaires and surveys were used to collect data on the Quality of Life (QOL) of the patients as well as on patient satisfaction. These questionnaires are presented in Appendix 3. The Kidney Disease Quality of Life (KDQOL) and the European Quality of Life surveys (EuroQOL) were used to gather information regarding quality of life. The patients completed satisfaction with life, care, and telemedicine questionnaires for 5 quarters. All of the results of these questionnaires were stored in an Access database and analyzed in the final year of the project.

The strategy for the evaluation of the clinical aspects of Project Phoenix was to work systematically through the major measurement groups of this research. We analyzed data based

on 1) Kt/V; 2) patient satisfaction; and 3) patient reported quality of life. In this final report we summarize 1) the sampling procedures and resultant sample of patients; 2) the major exogenous and endogenous measurements used for this project; and 3) the results.

5.1.1 Sample Selection

The data collection phase of this project began in January 1997 and ended in January 1999. During this period, approximately seventy-three patients with end stage renal disease (ESRD) participated in 1,134 kidney dialysis sessions. Monthly levels of Kt/V—the primary endogenous measure of the study—were calculated for study participants. Kt/V represents a measurement of the dialysis dose: the measurement takes into account the efficiency of the dialyzer, the treatment time, and the total volume of urea in the patient's body.

Since patient Kt/V levels were central to this research, the final sample for all aspects of the clinical evaluation was based on all patients with valid Kt/V measurements. As anticipated, three factors produced values of Kt/V that were considered invalid:

- 1) measurement error;
- 2) advanced vascular access problems for which no amount of dialysis could improve these patients' Kt/V levels; and
- 3) new patients to dialysis among whom extreme scores are more likely

To identify Kt/V measurements that were produced by one of these three factors, each patient's Kt/V measurement was converted to a z -score based on his or her average Kt/V measurement. Consider a patient who had an average Kt/V measurement of 1.5 and a standard deviation of 0.2 during this study. If the patient's first dialysis session produced a Kt/V value of 1.4, his or her z -score distributed Kt/V score is -0.5.

Assuming a normal distribution of Kt/V measurements, z -distributed measures have known characteristics, most importantly, fixed proportions of cases under different areas of a normal cumulative density function. In short, patient Kt/V measurements that exceeded ± 2 z -scores were considered extreme cases – that is, the measurements were sufficiently different from average for a patient to warrant further analysis. If a patient had at least one Kt/V measurement outside of these bounds, all of the patient's Kt/V information was examined for errors. Every

extreme measurement was attributed to one of the three sources of error discussed above. This led to the exclusion of seventy-four individual Kt/V measures and the exclusion of two complete sets of patient measurements. These decisions were based on the judgment of Dr. Winchester, our clinical nephrologist.

Table 1 below, presents summary statistics for the Kt/V measurement for all of the data collected, the extreme cases (ultimately excluded from the analysis), and the final sample used in this analysis:

Table 1. Summary Statistics for Kt/V Data
by Type of Sample

| | Original Sample | Extreme Measurements | Final Sample |
|-----------------|--------------------|-------------------------|-----------------|
| Mean Kt/V | 1.50 | 1.11 | 1.52 |
| Standard Dev. | 0.27 | 0.51 | 0.23 |
| Minimum Value | 0.05 | 0.05 | 0.62 |
| Maximum Value | 2.62 | 2.26 | 2.00 |
| Number of Cases | 1,134 | 74 | 1,060 |

The final sample included seventy-one patients who had a total of 1,060 dialysis treatments. The 1,060 Kt/V measurements were aggregated as an average value to each patient to produce a final data set with seventy-one patients—one record for each patient.

5.1.2 Variable Definition and Measurement

Control Measures

While the most significant endogenous measure used in this study was variances in patients' Kt/V levels, the most important exogenous measure used in this study was the type of treatment each patient received—standard care versus standard care supplemented by telemedicine. For example, one possible clinical outcome was that patients treated for kidney disease by telemedicine would exhibit greater average Kt/V levels than patients treated in a standard dialysis setting. Patients were not randomly assigned to these groups, a weakness of this study due to high cost of installing the telemedicine application at both centers and logistical

constraints associated with giving some patients at one center access to the telemedicine and not others. Instead, patients selected where they were treated (TRC Union Plaza or Georgetown-on-the-Potomac), which then determined what type of treatment they received (telemedicine and standard, respectively). This selection was coded as an indicator variable where 1 equals telemedicine treatment and 0 the standard treatment.

Other exogenous measures were used to provide statistical control for our analyses and included sex, number of dialysis treatments, race, education, income, average number of days spent in the hospital while active as a study participant, average number of medications while active as a study participant, and the total number of comorbidities. These measures are summarized in Table 2.

Table 2. Major Exogenous Variables

| | |
|--------------------|--|
| <i>N</i> | –number of dialysis treatments |
| <i>sex</i> | –an indicator variable where 0 equals women and 1 equals men |
| <i>treatment</i> | –kind of dialysis treatment, 0 equals standard dialysis and 1 equals telemedicine dialysis |
| <i>race</i> | –patient's race, 0 equals white and 1 equals minority |
| <i>education</i> | –patient's education, 0 equals low education, 1 equals high education |
| <i>days</i> | –average number of days in a hospital during the previous six months |
| <i>medication</i> | –number of medications the patient is currently taking |
| <i>comorbidity</i> | –total number of comorbidities for each patient |

Dependent Measures

The major endogenous measurements for clinical evaluation include Kt/V, three surveys of patient satisfaction (satisfaction with care, satisfaction with life, and satisfaction with telemedicine), and quality of life.

Kt/V is the major measure of both the efficacy of dialysis treatment as well as overall patient health related to ESRD. Technically, as we noted earlier, the Kt/V measurement takes into account the efficiency of the dialyzer, the treatment time, and the total volume of urea in the

patient's body. Longer periods spent on dialysis, per treatment session is believed to improve patient overall health related to ESRD.

Different survey instruments were used to evaluate patients' satisfaction with their care, their life, and their telemedicine experience. While there are too many variables to review here, most survey items could be answered by circling a value in a Likert type scale. For example, patients were asked: "In most ways my life is close to ideal." Possible responses included "Strongly Disagree", "Disagree", "Slightly Disagree", "Neutral", "Slightly Agree", "Agree", and "Strongly Agree." Table 3 presents the three most often used survey scales.

Table 3. Scales for survey instruments

| Scale 1 | Scale 2 | Scale 3 |
|-----------|------------------|-------------------|
| Very poor | Definitely True | Strongly Disagree |
| Poor | Mostly True | Disagree |
| Fair | Don't Know | Slightly Disagree |
| Good | Mostly False | Neutral |
| Very good | Definitely False | Slightly Agree |
| Excellent | | Agree |
| The best | | Strongly Agree |

Finally, patients' quality of life was measured by using the sub-scales of the Short Form-36 (SF-36) physical and mental health index and the scaled items from the Kidney Dialysis Quality of Life (KDQOL) form. The SF-36 is a well recognized mental and physical health index that is used to diagnose health and emotional problems in the elderly. It measures generic health concepts relevant across age, disease, and treatment groups and is comprehensive, psychometrically sound, and efficient. The core SF-36 questions were supplemented with questions specific to ESRD, forming the Kidney Dialysis Quality of Life form (KDQOL). These measures have been used in other studies, and like the SF-36, higher scores indicate better health than lower ones.

Measures were aggregated to the level of the patient, resulting in somewhere between thirty-four and seventy-one cases. Then, using simple *t*-tests, correlation coefficients, or Ordinary Least

Squares (OLS) regression, comparisons of outcomes (Kt/V, satisfaction, and quality of life) were made between patients utilizing telemedicine versus patients receiving standard treatment.

Demographic Information

In the final sample, thirty-two patients were women and thirty-nine were men. As expected, since women generally have lesser distribution volume of water, in our study their average Kt/V values are greater than those of the men (1.53 versus 1.46, respectively—however, the difference is not statistically significant). Table 4 details the distribution of men and women across the major explanatory measure, standard versus telemedicine dialysis treatment:

Table 4. Distribution of Sex Across
Standard and Telemedicine Treatment
Sites

| | Standard (<i>n</i> =32) | Telemedicine (<i>n</i> =39) |
|-------|-----------------------------|---------------------------------|
| Men | 43.8% | 46.2% |
| Women | 56.2% | 53.8% |

Because a rolling admissions process was used to recruit subjects for this study, there was some variability in the number of dialysis treatments received by each patient, and therefore the number of Kt/V measurements collected. The number of monthly Kt/V measurements for each patient ranged from two to twenty-four. On average, patients had fifteen Kt/V measurements. The average number of Kt/V measurements was higher for the standard treatment group than for the telemedicine group (16 versus 14 measurements – however, the difference is not statistically significant).

Table 5. Distribution of Number of Kt/V Measurements Across Standard and Telemedicine Treatment Sites

| | Standard (<i>n</i> =32) | Telemedicine (<i>n</i> =39) |
|-------|-----------------------------|---------------------------------|
| 0- 5 | 6.2% | 10.3% |
| 6-10 | 15.6% | 25.6% |
| 11-15 | 9.4% | 20.5% |
| 16-20 | 34.4% | 23.1% |
| 21-25 | 34.4% | 20.5% |

Study participants self-identified their race according to the following categories: African-American, Hispanic, American Indian, Asian, and White. Table 6 details the distribution of race across telemedicine and standard treatments:

Table 6. Distribution of Race Across Standard and Telemedicine Treatment Sites

| | Standard (<i>n</i> =30) | Telemedicine (<i>n</i> =38) |
|------------------|-----------------------------|---------------------------------|
| African-American | 50.0% | 94.7% |
| Hispanic | 10.0% | 0.0% |
| American Indian | 0.0% | 2.6% |
| Asian | 10.0% | 0.0% |
| White | 30.0% | 2.6% |

While it may appear that African-American patients were overly represented in this study, particularly in the telemedicine group, demographical studies suggest that African Americans suffer from end stage kidney disease disproportionately; while they account for about 30 percent of the patients who have this serious illness, they make up only 12 percent of the U.S. population. (See “Ten Facts about African-Americans and Kidney Disease, at: <http://www.kidney.org/general/news/african-american.cfm>)

Education and income levels were measured as categorical values to minimize respondent recall error. Study participants were asked how much education they had completed within the following categories: 8th grade or less, some high school, completed high school or GED, some college, completed college, at least some graduate education. Generally, the telemedicine patients are not as highly educated as the standard treatment patients, as indicated in Table 7.

Table 7. Distribution of Education Across Standard and Telemedicine Treatment Sites

| | Standard (<i>n</i> =30) | Telemedicine (<i>n</i> =38) |
|-------------------------------|-----------------------------|---------------------------------|
| 8 th Grade or Less | 3.3% | 10.5% |
| Some High School | 10.0% | 31.6% |
| High School | 26.7% | 15.8% |
| Some College | 16.7% | 29.0% |
| College | 30.0% | 10.5% |
| Graduate Education | 13.3% | 2.6% |

Study participants were asked to categorize their household income according to the following categories: less than \$5,000; \$5,001-\$10,000; \$10,001-\$20,000; \$20,001-\$40,000; \$40,001-\$75,000; and greater than \$75,000. Results are indicated in Table 8.

Table 8. Distribution of Income Across Standard and Telemedicine Treatment Sites

| | Standard (<i>n</i> =25) | Telemedicine (<i>n</i> =36) |
|-------------------|-----------------------------|---------------------------------|
| LT \$5,000 | 12.0% | 19.4% |
| \$5,001-\$10,000 | 8.0% | 38.9% |
| \$10,001-\$20,000 | 20.0% | 13.9% |
| \$20,001-\$40,000 | 8.0% | 13.9% |
| \$40,001-\$75,000 | 28.0% | 11.1% |
| GT \$75,000 | 24.0% | 2.8% |

Each study participant was asked to estimate the number of days he or she had been in a hospital during the previous six months. Responses were averaged across the number of quarterly reports completed by each participant. Average hospital stays ranged from none to seventy days. The average number of days in a hospital was approximately seven (with a standard deviation of thirteen).

Study participants provided information concerning the number of medications they were currently taking. This is a proxy measure for degree of illness, one which assumes healthier patients require fewer medications. This measure ranges from 1.2 to 12 with a mean of 5.2 (standard deviation=2.3). As we conclude from the numbers gathered (indicated in Table 9), there is a statistically significant difference in the average number of medications across treatment conditions, with the telemedicine group having a higher average number (5.7) of medications than the standard group (4.5).

Table 9. Distribution of the Average
Number of Medications Across
Standard and Telemedicine Treatment
Sites

| | Standard (<i>n</i> =30) | Telemedicine (<i>n</i> =38) |
|-------|-----------------------------|---------------------------------|
| 0-3 | 26.7% | 15.8% |
| 4-6 | 53.3% | 55.3% |
| 7-9 | 13.3% | 18.4% |
| 10-12 | 6.7% | 10.5% |

Finally, patient comorbidities were recorded based upon indications in patient records. Presumably, the greater the number of comorbidities present, the sicker the patient, and the less likely it is that his or her Kt/V measures will be large. The average value of this measure is 1.3 with a standard deviation of 0.7. The range of possible values ranged from zero to three and were distributed as follows:

Table 10. Distribution of the Number of Comorbidities Across Standard and Telemedicine Treatment Sites

| | Standard (<i>n</i> =31) | Telemedicine (<i>n</i> =38) |
|---|-----------------------------|---------------------------------|
| 0 | 3.2% | 13.2% |
| 1 | 80.7% | 39.4% |
| 2 | 16.1% | 34.2% |
| 3 | 0.0% | 13.2% |

In summary, on average, the patients in our study undergoing treatment for end stage renal disease using telemedicine were more likely to:

- be a minority
- have lower income and lower level of education
- be taking a greater number of medications
- have a greater number of comorbidities
- have spent less time in a hospital

5.1.3 Summary of Results

The results of our study are mixed, with results obtained sometimes as hypothesized, but often not. If we had found a large number of statistically significant differences, statistical power would not be an issue. However, this study has low statistical power and therefore prevents us from having a great deal of confidence that where we have failed to find a significant difference, we have made a good decision. In the following section we will summarize the results of the clinical evaluation by the major endogenous measures-- Kt/V, patient satisfaction, and patient quality of life.

Analysis of Kt/V

Results favoring telemedicine should show Kt/V measurements that are greater on average for telemedicine patients than for standard dialysis patients. Table 11 summarizes the difference in the average Kt/V levels for patients who received standard dialysis treatments versus patients who received telemedicine treatments:

Table 11. Summary Statistics for Kt/V Data by the Type of Treatment

| | Standard | Telemedicine |
|--------------------|----------|--------------|
| Mean Kt/V | 1.55 | 1.44 |
| Standard Deviation | 0.19 | 0.20 |
| Minimum Value | 1.12 | 0.88 |
| Maximum Value | 1.87 | 1.72 |
| Number of Patients | 32 | 39 |

Without additional statistical controls, there is a slight difference in the average Kt/V levels, with patients receiving standard dialysis treatments exhibiting higher levels of Kt/V. However, this difference is neither statistically nor substantially significant.

We also employed a multivariate analysis to try to explain the difference in average Kt/V across the treatment groups by estimating the following regression model:

$$kt / v = \hat{b}_0 + \sum_{j=1}^8 \hat{I}_j + \hat{b}_9(treatment) + e$$

In this model, λ symbolizes an array of exogenous variables discussed earlier so we can examine the “pure” relationship between type of treatment and treatment outcome. The resulting coefficients are presented in Table 12.

Table 12. Regression Analysis
Comparing Telemedicine Versus
Standard Dialysis Treatments

| Variable | Parameter Estimate |
|------------------|--------------------|
| <i>intercept</i> | 1.41 (0.07) |
| <i>N</i> | 0.01** (0.004) |
| <i>sex</i> | -0.07 (0.04) |
| <i>treatment</i> | -0.09 (0.04) |

*=0.05; **=0.01; ***=0.001

Numbers in parentheses are standard errors

In general, the overall model is statistically significant and explains twenty-two percent of the variance in the Kt/V measurement. However, only one variable is statistically significant—the number of dialysis treatments a patient received. In summary, the average Kt/V levels for the telemedicine patients are not significantly different than those for the standard dialysis patients.

Analysis of Patient Quality of Life (QOL)

In general, QOL should correlate with physical factors like the Kt/V levels of the patients—in particular, higher Kt/V values should be associated with higher values on the QOL scales.

Examining the bivariate correlation coefficients between the major independent measures, we found:

- The correlations are mixed with little consistency, but are often in the expected direction.
- The correlations between Kt/V and QOL measures are low and not statistically significant, but almost all of the coefficients are in the anticipated direction (positive).
- Comorbidity behaves as one would expect with most of the coefficients in the appropriate direction (negative), and some are statistically significant.
- Some statistically significant correlations show that the telemedicine patients report better health and physical functioning than the standard treatment patients.
- Men report lower values of sexual and social functions compared to women.

- Being a minority is associated with lower values of the burden of kidney disease, work status, pain, and general health, where lower values indicate worse health or functioning.
- Patients with high income are more likely to report greater work function.

Analysis of Patient Satisfaction

Research subjects were surveyed about their satisfaction with their care and treatment as well as the use of telemedicine in treating ESRD. We collected data on

- 1) satisfaction with care
- 2) satisfaction with life
- 3) satisfaction with telemedicine.

Across each survey instrument we found that

- 1) patients tend to be very satisfied with their medical treatment
- 2) there are no significant differences in satisfaction between telemedicine and standard ESRD treatment on survey items asked of both groups
- 3) the telemedicine participants did not express concern about their treatment, telemedicine, or the use of technology in general.

The major findings are summarized below:

Satisfaction with Care:

- Nearly seventy percent of the patients responded that the doctors and staff were friendly and interested in the participant as a person.
- Approximately seventy-four percent of the respondents felt that it was at least mostly true that the staff encouraged them to be independent.
- Approximately eighty-three percent reported that the staff supported them in coping with their kidney disease.
- Satisfaction levels were high on these items across the treatment sites so that there is no statistically significant difference between the telemedicine and standard treatment groups.

Satisfaction with Life:

- Nearly twenty percent of the patients were “neutral” when asked if their life was close to ideal; with the remainder roughly split between agreeing and disagreeing with this statement.
- Sixty-two percent of the respondents at least slightly disagreed that “the conditions of my life are excellent.”
- Similarly, approximately sixty-five percent of the respondents at least slightly disagreed with the statement “If I could live my life over, I would change almost nothing.”
- There were no statistically significant differences in overall satisfaction with life across treatment site except for the final statement “If I could live my life over, I would change almost nothing.” The telemedicine participants were less likely to agree with this statement than the standard treatment group.

Satisfaction with Telemedicine:

- In general, there was little variance in participants’ responses—most people were satisfied with their telemedicine treatment.
- Study participants using telemedicine were not concerned about privacy, using the technology, and not being physically present with their doctor.
- They felt that they had more control over their disease.

By January 2000, the patient satisfaction data were coordinated with the coded doctor and patient interactions and patient interviews. This allowed us to explore patient satisfaction from a patient perspective and an interaction perspective, and the changes in perceptions about telemedicine over time. We also explored whether the themes developed from the interview data--namely control over disease management, degree of uncertainty, and co-creation of a communications environment coincided with the coding of patient and doctor interaction. In addition to providing us with information regarding patient satisfaction and perceptions of telemedicine, these data provided us with the opportunity to explore the variance in data received through qualitative versus more quantitative methods.

5.2 Physician – Patient Interaction Analysis

5.2.1 Data Collection

In addition to the patient folders, patient session forms were developed by the Clinical Team for both telemedicine and physical sessions, to track more comprehensive patient information.

Summer interns observed 3-4 physical rounds and telemedicine consults per week capturing the data. The data collected include:

- type of consult (telemedicine or physical)
- social discussion
- clinical discussion (medication refill, access problem, change in dialysis prescription, referral, medication change, travel related, reports discussion)
- patient complaint (clinical, non-clinical)
- discussion with family member
- confidential discussion
- physical check (by physician or nurse)
- education
- interruption (other patient, phone call, pager, other)
- special situations (patient sleepy, patient does not want to talk, other)
- technical problems (no sound, system frozen, system crash, time to recover, other)

For our own studied focus on telemedicine outcomes, we consistently collected data of both the physical rounds and telemedicine consults. Three-to-four physical rounds and telemedicine consults per week were observed by our Clinical Team and data gathered from each one.

By January 1999, the data collection for 50 telemedicine and physical consults at Union Plaza had been completed with data collection from the physical rounds at GUMC continuing. The goal was to have 50 consults from each of the 3 areas under study: telemedicine at Union Plaza, physical rounds from Union Plaza, and physical rounds at Georgetown. By April 1999, this approximate number was attained (47 telemedicine consults, 51 physical consults at Union Plaza, and 49 physical consults at GUMC), and at this point we felt our goal was reached.

Preliminary analysis of our data began by July 1999. We discuss these findings in some depth in the section below. However, at this point, we wish to describe some significant findings from analysis of our preliminary qualitative analysis of interview data. We feel that these findings say much about the use of telemedicine and the kinds of information we could expect to gather and what stipulations, both technical and clinical, could prevent us from access to certain detail.

5.2.2 Preliminary Interview Data

Patient interviews undertaken early in the project explored the patients' interpretations of the communicative context provided by videoconferencing clinical consultations. Using an in-depth interview guide, we asked patients participating in the telemedicine group to discuss their understanding of how the videoconferencing technology influenced communications among the physician, nurses, and themselves. Twelve of the telemedicine patients were interviewed, as were two nurses from the dialysis center. Two researchers were present at each interview, one conducting the interview, the other taking extensive notes. Each interview lasted approximately 45 minutes and took place after the patients' hemodialysis sessions were completed. Extensive notes from these interviews were transcribed and coded to develop themes for the subsequent analysis segment of the project. See Appendix 4 for the list of questions which patients addressed.

5.2.3 Initial findings

Preliminary analysis of the interview data from the 12 telemedicine patient interviewees provides interesting implications. A telemedicine clinical consultation constitutes a dramatic change in the communicative interactions that take place between doctor and patient. Previous research suggests that patients are generally satisfied with telemedicine consultations and rate them as very similar to face-to-face encounters. Telemedicine, despite its varied, possible applications, appears to be viewed generically.

Our initial analysis of findings about patients' perceptions of telemedicine consultations is that patients actually make clear distinctions regarding their expectations toward telemedicine care. Patients describe specific conditions under which telemedicine care is and is not appropriate. Each of these conditions relates to the ability of the technology to mediate communications

between physician and patient. These conditions involve several categories, which are: patients' control over disease management; patients' degree of uncertainty; and the patients' and physician's co-creation of the communication environment. We discuss these three categories in some detail as follows.

Availability. Research exploring hemodialysis patient-physician relations suggests that patients' most notable complaint relates to the unavailability of the physician. The initial analysis of our interview data suggests that patients' primary reason for satisfaction with telemedicine consultations relates directly to their increased access to the physician. Because telemedicine adds an extra scheduled visit with the physician each week, patients are provided with an additional opportunity to confirm their status. Patients refer to telemedicine as a good "in-between visit." Our patients noted the efficiency that telemedicine provides the physician by saving him a trip to the dialysis center while still providing scheduled contact. One patient noted: "Telemedicine is a way to see your doctor more often. You are under better care that way."

Most emphasized by the patients was the benefit of real-time visual contact. In fact, in stressing the benefit of visual contact, many patients suggested that there was little to no difference between being in the same room with the physician versus seeing him over the telemedicine system. Said one patient: "He can see me and I can see him... Seeing him makes it more personal. I like that. Even if he is not in person, having him face-to-face makes all the difference." Another patient underscored this point by saying: "There is no difference, here or on the TV screen monitor, it is the same."

Degree of uncertainty. Patients with ESRD constantly live with uncertainty about their health condition. Our data reveal that uncertainty could be classified into three primary areas: uncertainty with routine care, uncertainty related to a crisis in dialysis management, and uncertainty related to major re-directions of care. These are three very significant emotional events in our patients' lives and they warrant discussion:

Uncertainty with routine care refers to the management of everyday dialysis issues. The increased access to the physician was satisfactory when patients were doing well (blood pressure, fluid level, and access site were stable) and needed only a status check. Under these relatively routine conditions that were low in uncertainty, a telemedicine visit was usually perceived as

being comparable to a traditional visit. One patient said: “Telemedicine is good for those patients that only need to see their doctor once a month.” This comment suggests that telemedicine should be used with patients who are “well enough” to require that level of care.

Uncertainty related to a crisis in dialysis management refers to an unexpected emergency, such as a precipitous drop in blood pressure while connected to the dialysis machine. During a crisis situation, patients see telemedicine as an effective way of communicating with their doctor. The doctor can visually examine the patient, monitor physiological signs, and communicate with the patients in a richer environment than that offered by telephone.

One patient suggested that telemedicine should be available 24 hours a day, so that the visual contact would also be available to the physician in case of an emergency. Another patient said: “TV helps in an emergency, if you really need something, he can respond.” This desire for availability coupled with the advantage of visual contact suggests that some patients see telemedicine as a replacement for the phone, but not necessarily for face-to-face contact, as the comments suggest in the next segment.

Uncertainty related to a major re-direction of care refers to changes in the dialysis regimen. These might refer to medication changes, or problems with a graft or access site. When the doctor was re-directing care, thus creating uncertainty in the patient, patients tended to prefer a traditional face-to-face visit. Patients noted the need for the doctor’s direct interventions, so as to remove the ambiguity from the situation. Some patients even save information pertaining to major care re-directions from one face-to-face visit to another, rather than talk about it during a telemedicine visit. Some examples of cases when patients need to see the physician in person are noted in the following.

One patient suggested that medication changes required an in-person visit. He said, “It’s [telemedicine] pretty good but when the doctor changes your prescription, I wait until the doctor comes in person, then I get the prescription myself and take it to the pharmacy.” Other patients suggested that access problems required an in-person visit. One patient noted, “Yesterday, they couldn’t stick me right. I would have liked to have Dr. W here to look at my access and talk to the surgeon about it.” Another patient said, “When I have a graft problem, I would rather see him in person, but the TV is okay.” One patient suggested that if he felt sick, he would rather see the doctor in person, “When I feel really bad.

Sometimes on Monday when I have too much fluid, I would like to see him in person...he can see me in person, see what's wrong with me, examine me.”

These comments concerning patient uncertainty and the use of telemedicine suggest the following model for directing telemedicine care:

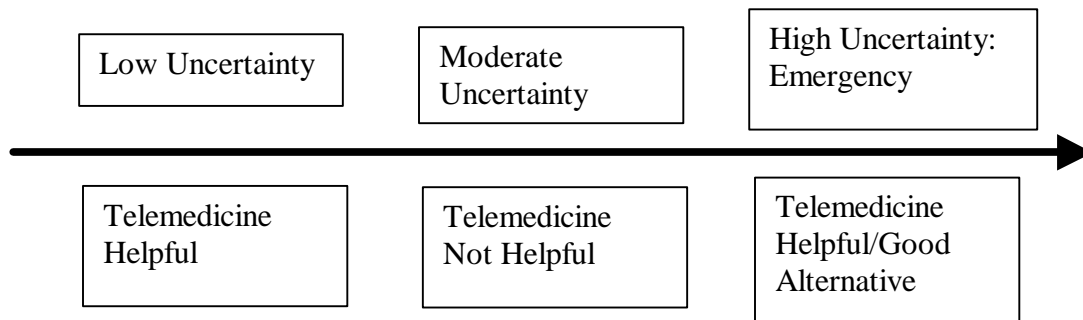


Figure 1. Model for Directing Telemedicine Care

“Presence” offered by telemedicine for ESRD patients, or co-creation of the communications environment

Contributions by both the doctor and patient comprise the interaction during a clinical consultation. In a telemedicine encounter, each participant contributes to the creation of a new, virtual communications environment. This environment is distinct from the traditional environment and is co-created by the participants. As a new environment, it requires the development of new norms and protocols for communication. We found that patients experiencing a major redirection of their treatment might prefer a communicative environment or “presence” that permits touch and physical presence. These patients may have higher relational needs. Patients experiencing routine consultations may be primarily interested in information exchange, and therefore are satisfied with the communicative environment that telemedicine provides.

The technical characteristics of the systems contribute to the creation of the new, virtual communication environment. In contrast to the traditional visit, the telemedicine visit limits the physician’s view of the patient to the image provided by the camera. Therefore, some patient’s felt that the physician could not always “see” how the patient was “really doing.” Said one patient, “He [the physician] can’t feel through the monitor or actually see what I might be complaining about...like a bruise...over the monitor

he is not here where he can see you in person, close-up. The monitor doesn't give you a sense of the person." Another patient said, "You need to see him face-to-face so that he can examine me and make sure that I am okay. Over telemedicine he might miss something." The telemedicine system also limits the ability of the physician to touch the patient. If the physician needs to touch the patient to feel something, he must have the nurse touch the patient and then communicate his/her findings to the physician. Some patients miss this touch. Said one patient, "Seeing him in person provides the hands-on personal touch. I wouldn't want to only telecommute."

Similarly, patients raised concerns with the system's audio capabilities and their own ability to hear the physician adequately. Other patients used the characteristics of the system to their own ends. For instance, one patient would talk about private matters over the system rather than during a conventional visit (at which other patients receiving dialysis are nearby) because of the added privacy of the headphones that prevented other patients from hearing his conversation.

On the other hand, some advantages of using the headset, such as contributing to the sense of "presence," were noted. Since the beds are relatively close together within the dialysis unit, patients used headphones to talk to the physician during telemedicine appointments. In some ways, the headphones made a telemedicine visit more private than an in-person visit since, during telemedicine visits, the other patients could not hear what the doctor was saying. However, since the nurse also wore headphones, patients would have to ask the nurse to remove the headphones in order to have a completely private conversation with the doctor. Said one patient, "The TV system is private. Nobody else can hear or butt in." This comment about "butting-in" referred to interruptions that often occurred during in-person visits. The doctor might be meeting with one patient and a nurse would come by during the session and ask the doctor a question or ask him to take a phone call. During telemedicine visits, since the doctor was not physically present to be interrupted, patients felt that the visit was more private.

Some patients also suggested that they behaved differently during telemedicine than during in-person visits. Said one patient, "I don't feel comfortable talking to a screen. If something is really important I would wait to ask him in person." Another patient said, "You don't know what to say over video...over video you have to think for awhile...you have to concentrate more." One patient admitted to using telemedicine as a means of monitoring what he disclosed to the doctor. Specifically, he said, "Sometimes I feel more comfortable when he is not here. When I goof up and gain fluid it is easier to tell him over telemedicine than face-to-face. I guess it is the kid in me. When your dad has to punish

you on the phone, it is not as hard as being in person. Over telemedicine I can avoid his eyes and look away. In person, I feel like I have to look at him. I am not really conscious of it. But when I have 9 or 10 kilos in me, I can look away. Don't have to see his expression. When he is here, I can't avoid it... I guess telemedicine could be a disadvantage to a patient over time since it is easier to feel like you can get away with cheating with the machine." No other patients mentioned or commented on their willingness to disclose over telemedicine versus in-person visits.

These interviews suggested that patients did perceive their communication during telemedicine visits to be different than in-person visits. As a result, we designed the coding scheme to help to understand these differences further.

Physician Perceptions

Discussions with the physician, Dr. James Winchester, the nephrologist for this project, revealed interesting insights. Dr. Winchester felt that telemedicine sessions took longer than in-person sessions. He also thought that telemedicine rounds tended to get boring. We note that he reported no difference in the interactions in general and could not describe a single instance when he needed to have an in-person visit to perform a necessary procedure while using telemedicine.

Nurse Perceptions

The nurse who worked with the telemedicine system, Marissa Hofelina, and wheeled the system from bed to bed, commented that she enjoyed the control that she had over the sessions. She was able to decide when the session between the physician and patient was officially over since she manually pushed the system to the next patient's bed. She did not perceive a difference between the telemedicine and in-person consultations.

5.2.4 Analysis of Coding Sessions

In response to findings from the interviews, we coded conversations between the doctor and patient by indicating on a coding sheet each time the following topics were introduced into the conversation: social/nonclinical topics, routine checks, medication refills, access problems, change in dialysis, referrals to other specialists, medication changes, medication orders, travel-related concerns, labs and reports, patient complaints, family discussions, confidential discussions, and patient education. We also coded special situations that might occur, such as

needs for physical checks (by the nurse or the physician), physician interruptions, times when the patient refused to interact, and technical problems. We also tracked consultation time. Between May 1998 and March 1999 we coded 147 patient encounters. Fifty-one were face-to-face encounters at Union Plaza/TRC, forty-seven were telemedicine encounters at Union Plaza/TRC, and forty-nine were face-to-face encounters at Georgetown University Medical Center. All patient encounters were coded using the same physician. Three coders were trained in use of the coding scheme and they maintained an interrater reliability of .95, indicating close to complete agreement on the coded items. If the topic came up during the interaction, the topic received a 1; if not, it was coded a 0. A section was added so that the coder could include anything that occurred during the interaction that was not included in the coding scheme.

5.2.5 Preliminary Findings

We totaled the topics of interaction to create the variable total interactions for each session. We then compared the total interactions between telemedicine and face-to-face conditions. We found no significant difference between the telemedicine and face-to-face conditions at Union Plaza. We also found no significant difference between the total interactions at Georgetown versus those at Union Plaza. Therefore, although the interviews with patients suggested that they might introduce more topics during face-to-face than during telemedicine consults, the coded sessions did not reflect that finding.

5.2.6 Further Analysis of the Coded Sessions

Demographic Differences

To take advantage of the data collected on patients' education, race, gender, socioeconomic status, and degree of sickness, we used a number of variables to determine whether patients differed in their discussion of topics based on these demographics. We used OLS regression to model the total of all clinical interactions as well as all interactions as a function of the total number of telemedicine versus face-to-face sessions, race, sex, education, income, and comorbidity. These measures are defined elsewhere in this final report. Our general model was:

$$D.V. = \hat{b}_0 + \hat{b}_1(sex) + \hat{b}_2(race) + \hat{b}_3(education) + \hat{b}_4(income) + \hat{b}_5(comorbidity) + \hat{b}_6(\#sessions)$$

where *D.V.* represent our two dependent measures of interest, total clinical and total interactions. Our results are presented in Table 13. Only one measure is statistically significant and it was in the predicted direction—the total number of dialysis sessions. In other words, we found no evidence of greater, or lesser, interactions between patients and doctors based on sex, race, education, income, or comorbidity.

Table 13. Regression Results for Patient/Doctor Interaction Models.

| | Clinical Interactions | Total Interactions |
|----------------|-----------------------|--------------------|
| Constant | 1.14 | 2.19 |
| Sex | 0.66 | 0.43 |
| Race | -0.81 | -1.72 |
| Education | -0.26 | -0.88 |
| Income | 0.34 | 0.85 |
| Comorbidity | -0.19 | -0.43 |
| Total Sessions | 0.45*** | 1.87*** |
| r^2 | 0.41 | 0.78 |

* = 0.05

** = 0.01

*** = 0.001

Results are 2-tail tests.

Consultation Time Differences

Using an ANOVA, we found no significant difference of consultation duration time between in-person consultations and telemedicine consultations ($df=1, 145$; $F=2.719$; $p>.05$). When we compared each of the conditions (in-person/Georgetown, in-person/Union, and telemedicine/Union), an ANOVA revealed a significant difference between the conditions ($df=2,144$; $F=8.156$; $p=.001$). In-person consultations at Union Plaza took the longest (mean=3.39), followed by telemedicine consultations at Union Plaza (mean=2.30), followed by physical consultations at Georgetown (mean=2.18). These findings suggest that, in general, consultations at Union Plaza took longer than Georgetown, regardless of the technology. The fact that physical rounds took longer suggests that patients may have talked longer about specific topics in person than they did over telemedicine, even if there was no difference in the number of topics that they introduced.

Interruptions/Technical

Coders reported no interruptions during the telemedicine consultations. However, during the in-person consultations at Union Plaza, 11 of the 51 sessions experienced some type of interruption, with 6 sessions having 4 interruptions during a single session. Only 2 of the 47 telemedicine

sessions reported technical problems. Table 14 provides a summary of the findings within the three conditions and details the number of times each type of topic occurred.

Table 14. Summary of Findings Between Three Conditions
Indicates how many times the topic occurred

| | Union/Telemedicine (47 total) | Union/In Person (51 total) | Georgetown/In Person (49 total) |
|----------------------------|----------------------------------|-------------------------------|------------------------------------|
| Routine check | 47 | 48 | 47 |
| Social discussion | 9 | 8 | 28 |
| Medication refill | 4 | 11 | 4 |
| Access problem | 1 | 0 | 1 |
| Change dialysis | 2 | 2 | 3 |
| Referral | 3 | 7 | 4 |
| Medication change | 2 | 3 | 4 |
| Medication order | 0 | 0 | 0 |
| Travel related | 0 | 3 | 2 |
| Lab Reports discussion | 13 | 5 | 14 |
| Patient complaint | 15 | 16 | 10 |
| Family discussion | 0 | 0 | 1 |
| Confidential discussion | 1 | 1 | 0 |
| Physical check | 0 | 9 | 6 |
| Education | 2 | 12 | 11 |
| Interruption | 0 | 9 | 0 |
| Technical Problem | 2 | 0 | 0 |

5.2.7 Summary of the Communications Analysis

The results of the study of the communication taking place within the three conditions suggests that although patients perceive a telemedicine interaction as different than an in-person interaction, this perception does not seem to influence the topics that they bring up. The differences in consultation time suggest that the doctor and patient interactions take longer during in-person rounds than telemedicine rounds. This finding is particularly interesting since the physician perceived telemedicine rounds as taking longer.

These results support telemedicine as an effective alternative for end stage renal disease patients. However, the qualitative results suggest that implementers of telemedicine be aware of the patients' need for in-person interactions with the physician. Although the results suggest that there was generally no difference between telemedicine and in-person visits in terms of the

interactions that took place, it is important to remember that these patients knew that they would be able to see the physician both ways. If the patient was only allowed a telemedicine visit, the results may have been different.

5.3 Cost Evaluation

5.3.1 Data gathering issues

One major objective of this project was to evaluate the influence of telemedicine on the cost of providing care for dialysis patients. We were interested especially in the costs associated with utilization of health care services, as opposed to the cost of conducting telemedicine sessions.

Economic and cost data analysis was expected to be based on National Claims History (NCH) data, from HCFA, for 71 dialysis patients enrolled in this project. The period of data collection was to be limited to 6 months prior to the patients' entry into the study and until the termination of data collection. In effect, at least 3 calendar years were to be included in the data set. In addition, we were interested in both Parts A and B of Medicare data, which would provide a wealth of detail on inpatient, outpatient, and home health services and costs.

Part A data would include information regarding all ESRD-related services (by diagnostic code) -- inpatient, outpatient, and home health -- provided during that time. The part B data would include all procedures, their frequency, and Medicare's allowed charges. We also intended to obtain demographic data and benefit start date from HCFA's Enrollment Data Base. The latter would show us when an individual patient qualified for the Medicare ESRD coverage.

We learned from HCFA staff that obtaining this information would be both costly (since this is not a HCFA-funded study) and time-consuming (requiring perhaps as much as 6 months), and were advised to request the data from the United States Renal Data System (USRDS). We made formal application for those data on 27 March 2000, but as yet have not been informed by USRDS whether the request was approved.

Given the apparent unavailability of the Medicare claims data, we instead used the data obtained from patients on a regular (weekly) basis using the Health Care Utilization (HCU) forms shown

in Appendix 5. As part of the Project Phoenix study, participants were asked to complete a *Health Care Utilization* form weekly. Four questions were asked that concerned the amount of health care services utilized by each participant outside of their normal scheduled dialysis. The survey items are:

- 1) Were you hospitalized at all last week?
- 2) Were you treated at an emergency room last week?
- 3) How often did you visit your personal physician this past week?
- 4) How many home health care visits did you have this past week?

Although Medicare claims data often have certain problems (e.g., completeness, especially due to long lag time in filing and adjudicating claims), the data we used were also limited in two major respects. First, their accurate collection relied on patients' memories. Second, there was a significant percentage of missing data due to the fact that patients sometimes did not complete the HCU forms. Nevertheless, the data were sufficiently complete so that we were able to conduct analyses regarding use of the four kinds of services listed above (i.e., hospital, ER, outpatient, and home health).

Our general hypothesis was that participants using telemedicine would have a lower Kt/V levels, and hence be healthier than those receiving standard dialysis, and hence would utilize fewer health services apart from scheduled dialysis sessions. This hypothesis is based on the premise that telemedicine is medically beneficial. Therefore, we anticipated that participants using telemedicine would be healthier than participants receiving standard dialysis treatments. If this were true, it is reasonable to assume that telemedicine participants should receive less health care services outside of their scheduled dialysis sessions, reducing the overall cost of treating ESRD.

5.3.2 Initial Analyses

Use of healthcare services.

In our first set of analyses weekly data were aggregated by summing participant responses for two time periods—the first three months and the second three months of respondent participation. This allows us to see if the frequency of these “outside” medical events changes over the time of study participation. Further, we are able to see if there are differences between

standard and telemedicine treatment, with fewer outside medical events associated with telemedicine.

The following four tables present summary information based on the aggregated health care utilization information:

Table 15. Were you hospitalized at all last week?*

| <i>n</i> | 1 st Three Months | | 2 nd Three Months | |
|----------|------------------------------|--------------|------------------------------|--------------|
| | Standard | Telemedicine | Standard | Telemedicine |
| 0 | 66.7% | 71.8% | 80.0% | 76.9% |
| 1 | 20.0% | 23.1% | 13.3% | 7.7% |
| 2 | 3.3% | 2.6% | 3.3% | 15.4% |
| 3 | 6.7% | 2.6% | 3.3% | 0.0% |
| 4 | 0.0% | 0.0% | 0.0% | 0.0% |
| 5 | 3.3% | 0.0% | 0.0% | 0.0% |

* Percentages may not sum to 100% due to rounding.

Table 16. Were you treated at an emergency room last week?*

| <i>n</i> | 1 st Three Months | | 2 nd Three Months | |
|----------|------------------------------|--------------|------------------------------|--------------|
| | Standard | Telemedicine | Standard | Telemedicine |
| 0 | 63.3% | 69.2% | 83.3% | 76.9% |
| 1 | 23.3% | 20.5% | 10.0% | 7.7% |
| 2 | 13.3% | 10.3% | 3.3% | 12.8% |
| 3 | 0.0% | 0.0% | 3.3% | 2.6% |

* Percentages may not sum to 100% due to rounding.

Table 17. How often did you visit your personal physician this past week?*

| <i>n</i> | 1 st Three Months | | 2 nd Three Months | |
|----------|------------------------------|--------------|------------------------------|--------------|
| | Standard | Telemedicine | Standard | Telemedicine |
| 0 | 66.7% | 66.7% | 80.0% | 64.1% |
| 1 | 16.7% | 20.5% | 10.0% | 20.5% |
| 2 | 13.3% | 7.7% | 6.7% | 7.7% |
| 3+ | 3.3% | 5.1% | 3.3% | 7.7% |

* Percentages may not sum to 100% due to rounding.

Table 18. How many home health care visits did you have this past week?*

| <i>N</i> | 1 st Three Months | | 2 nd Three Months | |
|----------|------------------------------|--------------|------------------------------|--------------|
| | Standard | Telemedicine | Standard | Telemedicine |
| 0 | 93.3% | 100.0% | 93.3% | 100.0% |
| 1+ | 6.7% | 0.0% | 6.7% | 20.5% |

* Percentages may not sum to 100% due to rounding.

The results were mixed, and apparent differences between groups were not significant. In general, comparing within the time periods but across the treatment sites, many of the results were in the predicted direction but none were statistically significant. For months one through three, telemedicine participants were on average less likely to be hospitalized, treated at an emergency room, and to have home health care visits compared to standard treatment participants. There was no difference in the average number of visits to personal physicians.

This pattern was reversed for months four through six. Here, standard dialysis participants were on average less likely to be hospitalized, be treated at an emergency room, and visit their personal physicians. Telemedicine participants were less likely to have had a home health visit, although, compared to the standard dialysis group the difference was small.

We also used ordinary least squares regression (OLS) to assess the effect of treatment condition (telemedicine or conventional), controlling for socio-demographic characteristics (sex, race, education, income), and medical factors (comorbidity, Kt/V). The results were uniformly non-significant, although many of the models provided regression estimates consistent with the

beneficial effects of telemedicine. However, regardless of which model we examined, none of the results were statistically significant.

For the analyses just discussed, we aggregated the data to two three-month periods. In doing so, certain detail in the data may have been lost. We therefore conducted a second set of analyses.

5.3.3 Monthly analyses of data

In the second set of cost analyses, we examined the use of health services, by month, for the first 6 months of participation in the study. Because of the large number of comparisons, in order to avoid inflation of the experiment-wise error rate, we used multivariate analysis of covariance (MANCOVA), with group membership as the main (fixed) factor, and sex, race, education, income, and number of comorbid conditions as covariates. Five separate MANCOVAs were computed—one each for hospitalization, hospital length of stay, emergency room visits, outpatient physician visits, and home health visits. Each MANCOVA contained 6 dependent variables (e.g., for hospitalization, the 6 variables were dichotomous variables reflecting whether or not a patient had been hospitalized during each of the 6 months analyzed).

As was the case in our aggregated analyses, no significant differences between groups were detected by four of the five MANCOVAs. These included hospitalizations, length of stay, emergency room visits, and home health visits. The groups showed a just significant difference with respect to the frequency of outpatient physician visits, although univariate analyses of variance showed significant differences only for month 2, while month 4 approached significance. Although most of the univariate comparisons were not significant, with the exception of the first month, when fewer telemedicine patients (78.1%) reported having had no outpatient physician visits than did control patients (92.3%), for every other month either the groups were approximately equal in this regard, or the control patients had more outpatient contact with their physician.

Analyzing the data on a monthly basis (as opposed to quarterly) provided a somewhat more detailed look at patterns of service utilization. However, apart from a trend for telemedicine patients to have fewer outpatient visits than control patients, there was considerable month-to-month variability for the other utilization measures, with no indication of a systematic difference.

5.3.4 Support for Project's Hypothesis

While we had hoped to find a statistically significant effect for the hypothesis that the use of telemedicine will reduce health services utilization, we are not disappointed with the results we got. There was a slightly significant effect, in the hypothesized direction, for outpatient physician visits; while for all other measures, the findings were not statistically significant. One conclusion that might be drawn from these findings is that telemedicine had little effect on service volume. While the data do not yield evidence that would falsify this assertion, the conclusion nevertheless seems to us somewhat premature.

We conducted *post hoc* analyses of statistical power (the likelihood that one will find a difference where one truly exists), and found that power approached the acceptable range (that is, ≥ 0.80) only for outpatient visits (0.74). For the four other variables, power ranged from a low of 0.18 (length of stay) to 0.30 (hospitalization). In other words, there was only a probability of 0.3 (less than 3 chances in 10) that if a difference in hospitalization frequency truly existed, it would have been detected). The most likely reason for the very low statistical power is the relatively small sample size. Also complicating the analysis was the fact that there were rather significant baseline differences between the telemedicine and conventional dialysis groups on a number of demographic variables.

5.3.5 Conclusions

Overall, the cost analyses were inconclusive. Neither treatment condition was demonstrably superior, although there were some mostly non-significant suggestions that telemedicine may be of some benefit in this regard. The most parsimonious interpretation of the results is that there were too few subjects, and too much within-group variability, to determine whether there were differences between the groups. Perhaps the inclusion of other risk factors in our statistical models would shed more light on the matter. Such variables might include length of time since beginning dialysis and etiology of ESRD, among others. The value of telemedicine in reducing health services utilization among dialysis patients remains to be demonstrated.

6 Home Peritoneal Dialysis (PD)

6.1 Introduction

Through the understanding and knowledge gained with the development and execution of the Renal Dialysis Patient Management (RDPM) network, Project Phoenix, an extension of this network to the home Peritoneal Dialysis (PD) patient was requested. These patients are responsible for providing their own PD on a nightly basis. Their responsibilities include performing scheduled cycles of PD and delivering prescribed volumes of peritoneal fluid. Since these patients provide their own dialysis, they are at increased risk for infection or from other occurrences that might not be recognized right away.

Patient's compliance with the PD prescription and recognition of initial stages of complications are critical to their continued success and maintaining their health. PD patients routinely visit the clinic once a month. If problems are encountered between visits, they can contact their clinicians or wait until their next visit. With the improvements in technology and advances in home communications, we proposed that the technology existed to better monitor these patients and ensure they are delivering the proper prescriptions. This part of the project provided a stronger link between the patient and their care team without additional burden to the patient.

Our focus at this point was on the technical feasibility of introducing tools to help patients on Peritoneal Dialysis better manage and track their disease while providing their clinical care team better access to the dialysis parameters. Baxter International was selected as the vendor to provide automated Peritoneal Dialysis (PD) equipment, the Home Choice Pro, to the project. We designed and developed a database and an interface between the Baxter's PD database and our own.

In addition, a patient-oriented Web site that is both appealing and easy to manipulate was designed. (URL: <https://mycareteam.georgetown.edu>) This site provides secure personalized information to the patients on the project. Patient data are displayed at the request of the patient and include PD parameters that have been acquired by the nurse, analysis of these parameters, lab values, current PD prescription, and reminders of appointments, tests, and other scheduled needs of the patient. There is also a range of educational and training information provided, such

as details on nutrition and exercise, as well as online communications capabilities for email with the care team and other study participants.

6.2 Operational Protocol

Three HomeChoice Pro devices were installed for three different patients. New telephone lines were installed in their homes so that the use of the HomeChoice Pro and Internet access would not interfere with their normal telephone. The operational protocol for this project involves the patients performing their peritoneal dialysis as required using the HomeChoice Pro device. The patients conduct their individual sessions as follows. Before they start each dialysis session, the HomeChoice Pro device prompts them to enter their pre-dialysis weight and blood pressure. Once the dialysis session is completed, they disconnect themselves from the device and set the device in “Modem Connecting” mode. This allows the nurses to dial into the modem connected to the HomeChoice Pro and capture the PD parameters stored in the HomeChoice Pro to be downloaded to the Baxter database. The three devices we deployed have been modified by Baxter Healthcare to increase the time-out period from 5 minutes to 8 hours. This allows the patients to set their devices to the “Modem Connecting” mode and their data can be captured, via modem, anytime within an eight-hour period. The patient does not then need to coordinate with the healthcare team to capture the data.

The benefit of using the HomeChoice Pro over the standard PD dialysis devices is that the HomeChoice Pro device uses a flashcard to store the PD parameters from each session. Standard dialyzers require the patients to maintain a paper log of the parameters from their dialysis session, including tracking their pre-dialysis weight and blood pressure. Now, the HomeChoice Pro can track all that for the patient and the patient no longer has to remember to bring that information to their physician during clinic visits. The care team has daily access to the PD parameters if needed.

6.3 PD Patients and Their Data

While the initial setup of the HomeChoice Pro devices did not always proceed flawlessly, the first two patients who received the HomeChoice Pro were very cooperative and compliant. They were patient with installation of the phone lines and setting up the devices, they use the device daily, and remember to put the machine in auto-answer mode most of the time. The third patient

was less cooperative and not as understanding about the special circumstances involved with participating in a research project. She used the device for only three weeks and then decided to remove herself from the project. There were problems with the telephone installation and the configuration of her machine and she was unable to deal with the uncertainty and additional effort required initially to start using the device.

For our two primary patients, we have 13 weeks of data for one patient and 8 weeks of data for the other. The second patient was removed from the HomeChoice Pro Device when he developed peritonitis and it was determined that performing manual exchanges of dialysis fluid was a better clinical option for him. He still has the HomeChoice Pro device at home and hopes to get back on the project.

6.4 Conclusion

We determined that the electronic capture of Peritoneal Dialysis delivery using a device like the HomeChoice Pro and the subsequent access to the collected data is feasible and not intrusive to the patient or care team. While our patients that were selected for this trial were compliant about recording their data manually, the on-line access to the PD parameters by the care team was particularly useful. At present the nurses have used the Web site to check on their patients several times per week. They used the system more than the project physician. This was not too surprising since PD nurses routinely play a very important role in the daily care of the PD patients. They tend to relay messages between the patients and the physicians. The Web site proved very helpful for them to easily see trends in the patients' data – especially ultra-filtration, blood pressure, and weight. We did not receive many comments from the patients, although one asked us to add pager information for the nurses, which we put on the project's Web site.

The development of the Web site is ever changing and improving. The feedback received from the nurses resulted in adding many new items to the lab results page, the patient alert and reminders page, as well as the education piece.

While we had hoped to have 5 – 10 patients on the site by the end of the project, we unfortunately never progressed beyond 3. We had not anticipated the delay in installation of the phone lines in setting our goals. The 2 patients who stayed with the project for the 2 – 3 month period did not take full advantage of the information on the Web site. They did not use the Web

site as frequently as we had hoped. We feel that one reason for this might be that the site was still under development when they were first given the HomeChoice Pro device. We provided a one-on-one training session for them after a couple of weeks, but they did not provide much feedback to us.

We feel that we accomplished a significant first step during this initial phase of our Home PD project by introducing nurses and patients to new equipment and new ways of undertaking their management of ESRD and PD. While our focus was on proving technical feasibility, we feel that this phase of the project was a success. Our hope is to extend this effort by improving on the Web site in terms of providing needed information that patients can use easily and productively and by doing a clinical trial with more patients in the future.

6.5 Ethical Aspects of Telemedicine-Supported HPD

The goals of studying the ethical aspects of telemedicine-supported home peritoneal dialysis (HPD) include the following: (1) to determine the specific burdens and benefits of using HPD, (2) to assess how telemedicine-supported HPD affects the distribution of burdens and benefits for patients and their family caregivers in managing HPD, and ultimately (3) to develop ethical guidelines for HPD delivery. In this project, we analyzed patients' and spouses' experience with telemedicine-supported HPD as a basis for developing ethical guidelines to help to identify the benefits and burdens of HPD in a way that advances the moral values of autonomy, well being, dignity, privacy, and confidentiality. As discussed in more detail subsequently, HPD should also meet the requirements for a minimum conception of healthcare justice that allow us to determine whether telemedicine-supported HPD as a type of home care technology promotes fairness, availability, access, and quality in treatment of End Stage Renal Disease (ESRD) inside and outside families. Overall, we believe that the development of specific ethical and clinical guidelines within a family-centered moral framework will help ESRD patients, their families, and healthcare providers determine an acceptable ratio of benefits and burdens when deciding to use HPD with and without telemedicine support in individual cases.

In this pilot study, we created and used a structured, open-ended interview instrument with an established set of questions to discuss with patients' and their spouses experiences with telemedicine-supported HPD. In general we evaluated changes in patients' and spouses' perceptions of benefits and burdens, as well as their moral status (e.g., autonomy, well being,

understanding, consent, and trust) as either enhanced, unchanged, or diminished through their experience with HPD and telemedicine technology. We expected these values to vary over time and in response to the complexities of their illness as well as a result of their interaction with the technology.

We interviewed two patients (Mrs. G and Mr. M) and their spouses. We interviewed all subjects two times, including a baseline questionnaire that focused on the history of the patient's illness and a follow-up questionnaire one month later designed to assess their experience with telemedicine-supported HPD (*See Appendices 6 and 7*). Interview data reveal that home-based peritoneal dialysis (HPD) has obvious benefits over traditional hemodialysis for our sample of patients and family caregivers. In general, HPD allowed dialysis patients and family caregivers more independence in activities associated with daily living and the management of dialysis treatment. In turn, patients and their spouses experienced improvements in their quality of life and a greater sense of well being. Given the short duration of patient experiences with telemedicine-supported HPD, our results remain preliminary. They nonetheless suggest that telemedicine adds no new burdens to the HPD process and potentially reduces some documentation burdens. Telemedicine appears to have no impact on physical burdens such as the weight of effluent bags, the cumbersome equipment design making travel difficult, and potential disruptions of dialysis from acts of God such as power outages. The role of telemedicine in educating and supporting families while using HPD remains a possibility.

6.5.1 Specific benefits

First, the two interviewed patients reported that they were able to be more involved in their own care and thereby be able to escape the traditional "patient" role as a passive object of treatment. For example, Mrs. G and her spouse discussed their satisfaction with being better able to adjust HPD treatment in a timelier manner because they had easier access to treatment data from earlier HPD sessions. Mrs. G also stated that hemodialysis, unlike HPD, subjected them to the demands and routines of a clinical schedule that regularly interrupted their home life and subsequently diminished their, privacy, well being and autonomy. Moreover, Mrs. G and her husband both found the hemodialysis clinic to be a "morbid" environment that depressed them and made them feel powerless over the management of Mrs. G's ESRD. HPD has minimized these sorts of stresses by increasing their ability to accomplish self-care routines. This, in turn, has enabled

them to some extent to remain hopeful about Mrs. G's future and to maintain a more positive conception of themselves as a couple in control.

Mr. M's experience with hemodialysis mirrored Mrs. G's. Mr. M reports that after only one month of hemodialysis he had "no life" because it took the whole day when travel time was factored in. In addition, Mr. M stated that he often felt alienated while at the hemodialysis clinic because the clinic regularly employed different technicians and medical staff, all of whom failed to get to know him well.

Second, when compared to traditional hemodialysis, patients and their spouses reported HPD to be less physically exhausting and time consuming, permitting them more time to engage in desirable activities. In Mrs. G's case, she has been able to continue teaching at a nursing school. Also, until her knees began to cause her problems, she was able to take care of the family garden, clean her home, prepare meals, and even fox hunt. In Mr. M's case, HPD has given him and his wife greater flexibility to travel, to care for their grandchildren, to garden, and to carry out a household renovation project.

6.5.2 Specific Burdens

Relative to traditional hemodialysis, HPD has many benefits. HPD nonetheless presented its own illness-related work challenges for patients and family caregivers, some but not all of which might change with telemedicine support. Our preliminary data suggest that HPD poses important physical burdens related to managing the equipment, namely lifting the effluent bags, transporting the dialysis machines, and manipulating odd mechanical features of the devices. The significance of such burdens, however, varied with important conditions related to the patient's illness trajectory phase and the availability of caregivers other than the spouse who potentially assume burdens when the patient weakens.

Chronic illness states develop trajectories; these are, the stable, unstable, improving, declining or unchanging pattern of an illness through time. Many conditions affect an illness' trajectory such as the biological progression of the disease, patient's access to care, or conditions in other aspects of a patient's life such as their work. With respect to understanding the impact of home care technology, as patients move from one phase (such as stable, unchanging) to another phase (such as, unstable, declining), the impact of a particular home care device or system might also

change. For example, if a device such as a home dialysis machine requires lifting heavy bags of fluid, a patient moving from a stable, reasonably well trajectory to an unstable, declining phase may lose the ability physically to manage the work associated with such a device thus requiring changes in how work gets accomplished and in the household's routines.

When we conducted our interviews, Mrs. G was in a stable phase of her illness and was awaiting a kidney transplant. Because of undetermined comorbidities, Mr. M in contrast was suffering a decline in his illness trajectory. So, whereas Mrs. G and her husband had established a routine and acceptable division of labor, Mr. M and his wife were renegotiating the implications of HPD for their lives and associated responsibilities.

The use of cyclor HPD to manage end-stage renal disease (ESRD) had a direct impact on the workloads and the division of labor within the families of interviewed patients. In Mrs. G's case, ESRD and her knee problems compromised her ability to perform most household chores, producing greater dependence on her husband, other family members and neighbors to perform household tasks. For example, Mrs. G and her husband reported that she was no longer able to grocery shop, cook meals, garden, nor was she able to perform the majority of the work related to HPD (e.g., change bags and maintain basic mechanical functions of cyclor HPD). The additional workload has had a profound effect on the life of Mrs. G's husband. For one thing, Mrs. G's ESRD and HPD have required him to retire early from his career and willingly take on the added responsibilities connected to her illness. Mr. G, however, has been able to distribute his new burdens and maintain some of his enjoyable activities and hobbies by training other family members and neighbors to help Mrs. G manage her ESRD and HPD when he needs a break or is unavailable to help Mrs. G.

Like Mr. and Mrs. G, Mr. M and his wife also experienced significant alterations in their daily workloads associated with Mr. M's ESRD, HPD and other illnesses. Unlike Mrs. G's spouse, however, Mr. M's wife continues to work long hours and is not available to her husband during most of the day. Moreover, Mr. and Mrs. M did not report any additional help from family and neighbors in the management of Mr. M's ESRD and HPD. As mentioned above, Mr. M was capable of gardening, watching his grandchildren, shopping, doing household chores, and various home renovation projects while his wife was at work. Recently, however, Mr. M. has entered a new destabilized and downward phase in his illness that has made these activities even

more difficult to carry out. In addition, Mr. G cannot safely drive because he now unexpectedly and frequently falls asleep and suffers periods of forgetfulness. This, in turn, has left him incapable of many household chores, such as shopping. Consequently, there are even greater workload responsibilities and less independence for his wife, who continues to work outside the home. In addition to new divisions of labor caused by HPD and Mr. M's recent physical and mental decompensation, the social life of Mr. and Mrs. M has also been significantly restricted. For example, their frequent excursions to shopping malls have sharply waned and nights out and vacations are becoming increasingly more rare for them. According to Mrs. M, the elimination of additional enjoyable and shared activities has caused her and Mr. M great distress. At this point, Mr. M and his wife's whole life together is undergoing fundamental and possibly irreversible change as they both assume more burdens associated with Mr. M's illness and illness-related work. Mr. and Mrs. M future is at best uncertain until the causes for Mr. M's precipitous decline are discovered and, hopefully, reversed.

These interviews strongly suggest that illness trajectory, familial support, and their matrix of personal values are more basic in shaping the relative benefits and burdens of HPD than the properties of the technology itself. At the simplest level, a device that an engineer finds simple or indeed intriguing might intimidate a patient with only an elementary school education. Or, a device that seems simple enough when a patient feels good and leads a more or less normal life might become overly burdensome given a decline in their condition. Alternatively, as a patient's illness trajectory improves, the feasibility of a particular home care device might increase. Our data supports this assumption for HPD technology use, including telemedicine-supported HPD. Understanding the conditions that regularly affect the impact of a home care device might help produce protocols for use in evaluating the feasibility and appropriateness of home care technologies in particular cases.

6.5.3 Family Justice

These points regarding feasibility of devices, identifying conditions needed for usage protocol development, and assessing the appropriateness of new technical devices to be used in the home pertain to the general problem of family justice in home healthcare. Justice in healthcare typically refers to fair distribution of benefits and burdens among individuals or groups of individuals, in particular, the benefits and burdens associated with achieving access to, paying

for, and managing healthcare services. In the G family's case, Mr. G retired from his work and willingly assumed responsibility for certain aspects of his wife's care. The problem was more difficult for the M family because Mrs. M had to continue working but Mr. M was entering a destabilizing and downward phase of his illness. Traditional approaches to healthcare justice are more than adequate when the interests of individual patients are being evaluated in relationship to large and often impersonal institutions, such as hospitals and the federal government. But, when we begin to speak of justice within the personal and intimate context of the family and home, justice takes on new and complex moral characteristics.

In the context of a traditional clinical setting, the patient's interests can and should be of primary importance, but in context of family and home the moral status and interests of family caregivers (i.e., the specific burdens and benefits they incur) must be given greater moral weight as family caregivers help to manage more of their sick family member's healthcare needs. Whether telemedicine-supported HPD constitutes an excessive burden or the promotion of patient and family autonomy and responsibility is less than clear at this point in time. Nevertheless, conflicts of interests normally not found in traditional medical settings, in which healthcare is governed by a *patient-centered moral framework*, will arise in the home. Hence, a *family-centered moral framework* will be necessary as more patients receive their care at home.

7 Data Security and Patient Record Confidentiality

7.1 Objective

This aspect of Project Phoenix intended to demonstrate a general approach for protecting the security and confidentiality of patient records in health applications of the National Information Infrastructure (NII). The Renal Dialysis Patient Management (RDPM) network and the Project Phoenix Testbed can illustrate security and confidentiality issues in health applications on the NII at all levels. We focused on understanding the organizational dimension of health information security, particularly the process of risk management and enhancing patient understanding of our efforts.

7.2 Risk Management

At the outset of the project, we completed a risk analysis of the paper-based RDPM system at the GUMC Dialysis Unit, which serves as the control site for Project Phoenix. In that document, we describe the facility, personnel, and procedures, and most importantly, evaluate the current level of security provided for patient records. We gathered the information by participating in mock dialysis sessions and extensive observations and interviews of staff and technicians. The latter activity provided insight into how patient records are created and updated, who has access to the information, what safeguards are in place to protect patient data, and what problems exist.

After completing a risk analysis of the paper-based RDPM system at the GUMC Dialysis Unit, we then proceeded to analyze the RDPM electronic network. The analysis was performed at the new TRC dialysis unit at Union Plaza, as well as at the Project's nephrologist's office and his home, all of which were connected by the telemedicine system put in place for this project. By October 1998, installation of a wireless computerized clinical information system known as HOMER had begun at the TRC Union Plaza site, and our team, led by Dr. Jeff Collmann, conducted a risk analysis on this system.

We hypothesized that electronic telemedicine systems, when managed according to established information security practices, provide increased access to and maintain the security of patient information, compared to patient-based medical records. We developed a set of comparative graphs illustrating that both paper-based and computer-based record system offer four possible options each with a different risk profile. Two dimensions combine to create the four options. The open-closed dimension refers to a record system's availability or connectedness to an untrusted network. Open systems offer their services to the public or are connected to an untrusted system. Closed systems limit the availability of the collection or are not connected to an untrusted system. The unrestricted-restricted dimension refers to the existence of controls governing access to a record system. Unrestricted systems lack access controls. Restricted systems maintain some kind of access control. This yields the four options: open-unrestricted, open-restricted, closed-unrestricted, and closed-restricted which decrease access and increase security, respectively.

Since our RDPM included a point-to-point T1 network with no connections to any network and no access to the computer-based network, and all its functionalities and the database required a password, it was a closed-restricted network. Moreover, the telemedicine devices resided within

restricted clinical spaces (the dialysis clinics) to which only patients, care providers and select family members had access (a second layer of controls yielding a closed-restricted record keeping system). In spite of these controls, however, the patients and care providers had better access to each other and to relevant clinical information using the telemedicine system in comparison to face-to-face, paper systems. Benefiting from and supplementing the controls of the paper-based record system but granting better access, the RDPM functioned as a more secure and more accessible system than the paper record.

7.3 Patient Consent

We hypothesized that, when properly informed about the institution's policies, procedures, and methods for maintaining the confidentiality of their medical records, patients will agree to using telemedicine systems and to storing their information in an electronic medical record. All patients received an overview of the telemedicine procedures, the risks involved in storing and transmitting confidential patient information electronically, and the steps taken to protect their data. Patients were then asked to consent to participate in the telemedicine study and to have their information stored in an electronic record. 87 of 92 hemodialysis patients signed consent forms agreeing to participate in Project Phoenix as subjects or controls and have study data included in a computerized patient record, a number so large that we had to rethink our understanding of the reasons why people might grant consent to participate in the project. We concluded utility of increased access far outweighed potential disutilities of data security or medical privacy, particularly for this population of chronically ill subjects. We also realized that consent, particularly among chronically ill patients, must function as a continuous process that expects potential changes in patients' need and desire for information as well as their willingness to participate in research varies with changes in their illness trajectory. "HelpBot", a web-enabled patient instruction tool instructing patients on Project Phoenix data security, grew from and contributed to this realization.

HelpBot

"HelpBot" enables patients and family members to explore our approach to data security as deeply as individuals required, simply by clicking through various levels of the tool. Four basic levels exist, including a homepage that introduces the whole project, a level that explains the telemedicine network, a level that explains the risks to data security found during our risk assessment of the telemedicine network, and a level explaining our risk management plan. A

user can migrate through the tool in an infinite number of ways depending on their own need to know and personal approach to learning. For example, if a patient wants to go straight from the beginning to the end, he can proceed horizontally from the introduction to the risk management plan. If a family member wants vertically to explore a particular component of the system, the telemedicine unit for example, she can click on the telemedicine unit, then click on the risks in the telemedicine unit and finally click on how the risks are being handled. At any point, a user can change the search pattern, return to the beginning or exit. In relevant sections, a user can activate hot links to other sites (for example, the firewall guide of the International Computer Security Association) while staying literally within the HotBot frame. We thus provide as detailed an explanation as possible of our approach to data security with the patient determining the level of detail actually searched.

HelpBot demonstrates our process of data security management as much as it explains its components. HelpBot explains that the telemedicine network exists physically in a particular setting, contains certain types of equipment, moves information along certain pathways, and depends on the actions of certain people. HelpBot also explains, however, that we performed a risk assessment of the telemedicine network; that is, we searched for risks to breaches of data security in the physical plant, the dialysis and telemedicine equipment, the information flow and the people. HelpBot also demonstrates that having identified the risks to data security, we developed policies, procedures and practices to secure the physical facility, maintain the equipment, manage the flow of information and educate the people. “HelpBot” illustrates how we would proceed given any other data security project. Thus “HelpBot” is both a model of and model for our approach to data security management at Georgetown.

We conducted a patient evaluation of “HelpBot”. Ten patients in Project Phoenix and members of their families used and evaluated “HelpBot” in the TRC Union Plaza waiting room. Overall, the patients found the HelpBot system easy to use in terms of presentation and language but many desired an audio option given their diabetes induced vision impairments. Many also suggested the addition of dietary information, a key concern of dialysis patients. Half of those surveyed indicated that reading about diets and medical information on their disease outranked learning about security and privacy.

7.4 Lessons learned from Project Phoenix

. Project Phoenix helped us develop general principles of how health care providers might prepare themselves to become data security capable organizations; that is, organizations in which assuring the security and confidentiality of medical information becomes incorporated into the every day working routines of all members of the organization, including patients. Building a security capable organization requires institutionalizing a security surveillance process, not just implementing security measures. Implementing a security surveillance process requires several steps, including:

1. Monitoring the changing legal and regulatory environment;
2. Continuously updating data security policies, procedures and practices in light of changing mission and;
3. Enhancing patient understanding of the organization's data security efforts,

Some of these tasks clearly fall under the responsibility of professional staff dedicated to managing medical records and information technology. When properly implemented, however, a comprehensive security surveillance process incorporates everybody including patients, vendors, business partners, individual staff, an organization's general administration and the data security team. Like universal precautions for infectious disease, we should recognize that breaches of security discipline threaten our employees, patients and organizations. Thus, maintaining the security of valuable medical information should become simply part of how we do our jobs rather than another in an ever-expanding list of onerous supplemental tasks. From this perspective, HIPAA constitutes a blessing disguised as regulation. HIPAA will help to focus administrative attention on and to institutionalize risk management in health information assurance. As we institutionalize data security surveillance, we should coopt, not simply coerce our health care colleagues into the process. After having begun the process, we should discover that we have created a new relationship with our "customers" in which we are accountable to them for our business practices in addition to our medical care.

We are in the early days of healthcare workers' appreciation of the importance of health information assurance. Although the principle of confidentiality has functioned as a primary support of the doctor-patient relationship in ethical terms, the demand for and accessibility of the patient chart as well as a tendency to treat hospital corridors as a private workshop makes

practice deviate often from principle. Security technology remains “extrinsic” to managing information: users must intervene at several levels from the direct human-computer interface to the architecture of LANs and WANs thus exacerbating the cumbersome practice, high cost and low priority of information assurance in everyday work. Because neither the final rules nor the “HIPAA police” yet exist, many organizations have adopted a “wait and see” stance catching up on projects deferred by Y2K rather than getting a jump on information assurance. Although a few health care organizations have recently lost important law suits over breaches of confidentiality and phenomena such as the “love bug” virus receive great public exposure, patient unrest over this issue nonetheless does not yet pose a serious routine challenge to the health care industry. Conditions for perceiving breaches of data security as threats to self, patient and organization have therefore not matured in the health care industry.

From this perspective, the proposed HIPAA data security and medical privacy rules potentially could improve the organizational climate for as well as specific practice of health information assurance. Even if particular health care organizations choose to adopt narrow constructions of “compliance”, HIPAA’s emphasis on risk management requires integrating health information assurance into their overall business missions, strategies and practices. A pitfall exists that could potentially undermine HIPAA’s organizational impact: outsourcing the process of preparing for HIPAA, particularly of developing, executing and evaluating the risk assessment. Although many organizations will necessarily subcontract aspects of HIPAA compliance to experts with special expertise such as vulnerability testing, health information assurance advocates should maintain control of the process and use HIPAA compliance as an opportunity for organizational growth. Unlike Y2K, HIPAA is forever thus giving health information assurance an opportunity to become institutionalized like infection control. We have adopted the position, therefore, that Project Phoenix represents a model for how health care organizations can internally develop and implement a health information assurance program. Because Project Phoenix focuses on the security of a small-scale network, it represents a particularly troublesome end of the “scalability” problem, small clinics and physician’s offices. Although our data security team originally included a formally trained computer security expert, we kept the work “in house” using techniques such as conducting the risk assessment, searching for a firewall and, indeed, studying the proposed HIPAA regulations themselves as opportunities for self-education and organizational growth.

7.5 Significant products of the Project Phoenix data security team

Developing tools and methods for enhancing awareness of sound information security policies, procedures and practices emerged as a major theme of the Project Phoenix data security team. We began our educational efforts with the members of the telemedicine research team, including both clinical staff in the dialysis centers and the ISIS engineering staff. We learned two basic lessons from our early training efforts: 1) experienced clinical staff believe that routine practices in health care organizations tend to undermine the confidentiality of the paper medical record, and 2) “getting the job done” (whether clinical work or information management) takes precedence over maintaining the security of the paper or computer-based medical record. In terms of the formal definition of security, we learned that clinical, administrative and information management staff more highly value access to the patient record than its confidentiality or integrity. At best, the work discipline thus entailed yields poor information security practices. At worst, staff disregard or override the requirements for confidentiality and integrity in their daily work. Achieving a thoughtful balance among accessibility, confidentiality and integrity requires structural changes in the relationship between clinical, administrative and information management staff and, fundamentally, training for everyone (staff, patients and vendors) in sound security practices.

1. *The CPRI Toolkit:* Jeff Collmann, Ph.D., leader of the Project Phoenix data security team, became the editor of a new tool for health care organizations in information assurance, known now as *The CPRI Toolkit: Managing health information security in health care*. *The CPRI Toolkit*, includes case material from Project Phoenix and PCASSO, the NLM-funded project on secure, remote patient access to the medical record. The concept of the “security-capable organization” developed as a result of Project Phoenix, structures the argument and the content of *The CPRI Toolkit*. Originally published in April 1999, *The CPRI Toolkit* has become widely known and distributed in the health care community. 3Com Corporation funded preparation and release of a web-enabled version that was announced as part of “Integrating across the Healthcare Enterprise” during the 1999 annual meeting of the Radiological Society of North America. As of April 2000, over 5000 copies had been downloaded from the website and over 1000 copies distributed as part of a seminar series on complying with HIPAA (see below). Version 3 was released in May 2000. Plans include updating and adding new content to *The CPRI Toolkit* approximately every six months. Appendix 8 includes the “Executive Summary”

of *The CPRI Toolkit*. Jeff Collmann and Ted Cooper made presentations explaining how to use *The CPRI Toolkit* at several national meetings, including the annual meetings of the American Medical Informatics Association, Health Information Management Systems Society, the CPRI, the American Telemedicine Association, and the Radiological Society of North America.

2. ***HelpBot:*** Informing patients about our efforts to assure the security of their information in the computer-based record system constituted a component of the process for obtaining consent from prospective participants in the telemedicine project. Our original design only included versions of the traditional, paper informed consent document. In order to take advantage of emerging web-enabled technology in the process of informing patients about security practices in Project Phoenix, we developed “HelpBot” and a tool for others to use in designing comparable devices. To consult “HelpBot” and the “How to” tool, please consult (<http://www.healthdatasecurity.georgetown.edu>). An article describing “HelpBot” appears in the CPRI newsletter, “CPRI Mail”.

3. ***Privacy, Security & Confidentiality of Medical Records: Complying With New HIPAA Requirements:*** Beginning in April 1999, Jeff Collmann, Ph.D., team leader of the data security team of Project Phoenix, moderated and spoke at a series of HIPAA-related seminars in more than twenty locations across the United States. Organized by Healthtech Strategies and Nonprofit Management Associates and sponsored by many organizations interested in HIPAA and health information security including the National Library of Medicine, over 1000 people attended the seminars. Michael Akerman, Ph.D. gave the keynote address at many of the seminars. The concept of “security-capable organization” structured the curriculum of the seminars as well as the content of *The CPRI Toolkit*, which each attendee received as the course text and syllabus. An example of the agenda appears in Appendix 9.

8 Publications and Presentations

8.1 Project Phoenix Team Members 1997 - 2000

Articles

1. Winchester JF, Tohme WG, et al (1997) "Hemodialysis patient management by telemedicine: Design and implementation", American Society of Artificial Internal Organs Journal, 43:M763-M766.
2. Collmann, J, Meissner, MC, et al, "Comparing the security risks of paper-based and computerized patient record systems: a case study of a renal dialysis telemedicine application", Medical Imaging '97, PACS Design and Evaluation: Engineering and Clinical Issues. Proceedings of the SPIE, 3035:172-182.
3. Meissner, MC, Collmann, J, et al, "Protecting Clinical Data in PACS, Teleradiology Systems and Research Environments", Medical Imaging '97, PACS Design and Evaluation: Engineering and Clinical Issues. Proceedings of the SPIE, 3035:183-190.
4. Tohme, WG, Winchester, JF, et al, "Design of a Multimedia PC-based Telemedicine Network for the Monitoring of Renal Dialysis Patients", Medical Imaging '97, PACS Design and Evaluation: Engineering and Clinical Issues. Proceedings of the SPIE, 3035:580-585.
5. Tohme WG, Winchester JF, et al (1997) "Remote Management of Hemodialysis Patients: Design and Implementation of a Telemedicine Network", Journal of Minimally Invasive Therapy and Allied Technologies, 6(5-6):421-428.
6. Tohme, WG, Wendelin, SH, et al (1997) "Requirements for urology and renal dialysis PC-based telemedicine applications: a comparative analysis." Telemedicine Journal 3(1): 19-25.
7. Winchester, JF, Tohme, WG (1998), et al. "Telemedicine and dialysis," Proceedings Pacific Medical Technology Symposium - PACMedTek, 116-118.
8. Collmann, J and A-L Silvestre (1998), "Building a Security Capable Organization," Proceedings Pacific Medical Technology Symposium – PACMedTek, 2-11.
9. Winchester, JF (1999), "Telecommunications and the dialysis patient", American Journal of Kidney Diseases, 34:xxxvi-xxxvii.
10. Collmann, J, Arwa Al-aama, AK, et al (1999), " HelpBot: Educating Patients Online about Health Information Security", CPRI-Mail, 8, (4), August.

Books & Chapters

1. Collmann, J, Cooper, T, et al (1999) The CPRI Toolkit: Managing Information Security in Health Care, Computerized Patient Record Institute: Bethesda, MD, 1999

2. Collmann, J, Cooper, T, et al (2000), The CPRI Toolkit: Managing Information Security in Health Care, 2nd Ed. Computerized Patient Record Institute: Bethesda, MD;and World Wide Web Edition, 3Com: San Jose, CA. 1999; 3rd Edition, 2000.
3. Collmann, J, “Reconciling European and American approaches to privacy” In Collmann, J., Cooper, T., et al (2000), The CPRI Toolkit: Managing Information Security in Health Care, World Wide Web Edition, 3Com: San Jose, CA. 1999; 3rd Edition, 2000.

National Symposia and Workshops

1. Collmann, J, [National Content Coordinator], “Privacy, security & confidentiality of medical records: Complying with sweeping new HIPAA requirements”presented in Washington, DC, Houston, TX, Denver, CO, San Francisco, CA, Seattle, WA, New York, NY, Atlanta, GA, Chicago, IL, Boston, MA, Dallas, TX, Washington, DC, and other cities, May 1999 through Spring 2000.
2. Collmann, J, 1999 HIPAA Summit, Baltimore, MD, October 11-13, 1999, Member of Executive Planning Committee.
3. Taylor, C, Dell’Oro, R, et al. “Workshop on Institutional Review Boards: Member Responsibilities and Related Competencies”, Center for Clinical Bioethics, Georgetown University, March 23-24, 2000.

Presentations

1. Winchester, JF, Tohme, WG, et al. “A hemodialysis telemedicine network,” Global Forum: A Bridge to the 21st Century. Tysons Corner, VA, March 1997.
2. Tohme, WG, Johnson, AE, et al. “Design and evaluation of a renal dialysis patient management network,” Proceedings of the American Telemedicine Association conference, Atlanta, GA, April 1997.
3. Winchester, JF, Tohme, WG, et al, “Hemodialysis patient management by telemedicine: Design and implementation”, Proceedings of the American Society of Artificial Organs Association, Atlanta, GA, May 1997.
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5. Tohme, W, Winchester, JF, et al, “Scrutinizing a Telemedicine Testbed: A Clinical Economics Model”, MedTec 97, Tysons Corner, VA, August 1997.
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9. Hoffman, L, "HelpBot -- a MultiMedia Tool to Describe Computer Systems and Educate Their Users", Workshop on Educational Modules in the Field of International Relations and Security, Zurich, Switzerland, November 21, 1997.
10. Collmann, J "Paper or Plastic?: Can the computerized patient record maintain confidentiality?", Ethics Grand Rounds, University of Tennessee Medical Center at Knoxville, December 6, 1997.
11. Winchester JF, "Project Phoenix: A telemedicine testbed in nephrology", American College of Physicians, New Mexico Chapter, Albuquerque, New Mexico, December 6, 1997.
12. Tohme WG, Winchester JF, and Collmann J, "Project Phoenix: A National Library of Medicine Dialysis Telemedicine Project", Joint Telemedicine Working Group, White House Conference Center, Washington, DC, January 1998
13. Winchester, J, "Telemedicine for dialysis," Presented at conference: Advances in dialysis adequacy, San Juan, PR, April 4, 1998.
14. Tohme WG, Winchester JF, and Collmann J, "Project Phoenix: A National Library of Medicine Dialysis Telemedicine Project", The Emerging Health Information Infrastructure (HII98), Georgetown University Conference Center, Washington, DC, April 26, 1998.
15. Winchester, J, "Use of telemedicine in the treatment of end-stage renal disease," presentation and panel discussion at Association for Health Services Research, National Library of Medicine Update, Washington, DC, June 21, 1998.
16. Al-Aama, A, "Help-Bot" series of presentations to Computer Security Systems course, George Washington University, Washington, DC, September 1998.
17. Winchester, J, moderated a course titled "Monitoring the Hemodialysis Patient: the Role of Telemedicine," Clinical Nephrology symposia, Annual Meeting of the American Society of Nephrology, Philadelphia, PA, October 1998.
18. Winchester, J, "Tele-nephrology," presented at Annual Meeting of the American Society of Nephrology, Philadelphia, PA, October 1998.
19. Levine, B, "Project Phoenix: A National Library of Medicine dialysis telemedicine project," presented at Annual Meeting of the American Society of Nephrology, Philadelphia, PA, October 1998.
20. Collmann, J, "Project Phoenix: A case study in building a security capable organization," Annual Meeting, American Society of Nephrology, Philadelphia, PA, October 25, 1998.

21. Winchester, JF, "Integrating informatics and telemedicine to improve clinical outcomes", DCA Foundation, Las Vegas, February 4-7, 1999.
22. Collmann, J "Building a security capable organization, "The Electronic Patient Record," DCHIMA, Bethesda, MD, March 12, 1999.
23. Winchester, J, "Telemedicine, the year 2000," Grand Rounds, Arlington Hospital, Arlington, VA, April 23, 1999.
24. Collmann, J, panel on health information security, HII99, Washington, DC, April 27, 1999.
25. Winchester, J, "Telemedicine, promise for dialysis," [invited lecture], National Kidney Foundation, Spring Clinical Meeting, Washington, DC, April 28-30, 1999.
26. Winchester, J, "Telemedicine, the year 2000," Grand Rounds, Georgetown University Hospital, Washington, DC, May 20, 1999. A live demonstration with Union Plaza of the Project Phoenix telemedicine system was provided for this meeting.
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33. Collmann, J and R Dell'oro, "Institutional Review Boards: A context for ethical discourse?" In Taylor, C. et al, Workshop on Institutional Review Boards: Member Responsibilities and Related Competencies, Center for Clinical Bioethics, Georgetown University, March 23-24, 2000.
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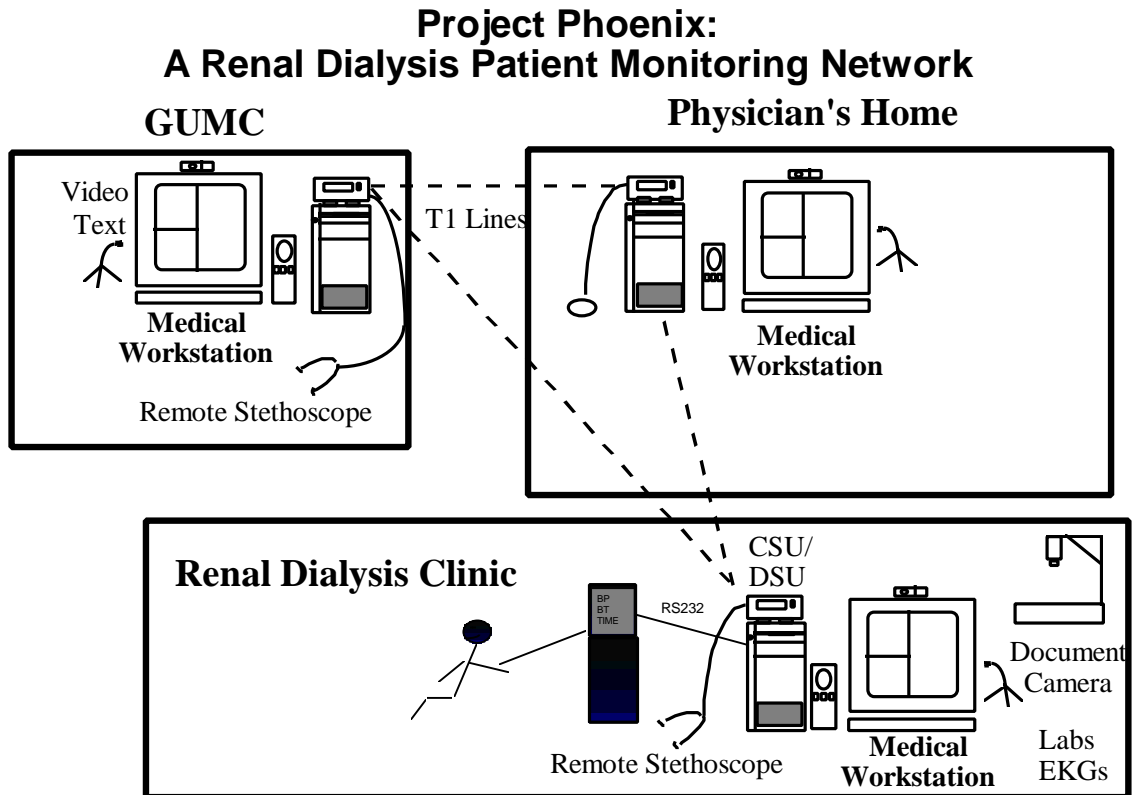
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37. Collmann, J, "Using the CPRI Toolkit" American Telemedicine Association, Annual meeting, Phoenix, AZ, May 23, 2000.
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2. "Hemodialysis and Telemedicine: Two Years Clinical Experience," JF Winchester, et al. Presented at the VIIth Congress of the International Society for Peritoneal Dialysis," Seoul, Korea, August 23-25, 1998.
3. "Telemedicine in Peritoneal Dialysis (PD): Study Design and Implementation," JF Winchester, et al. Presented at the VIIth Congress of the International Society for Peritoneal Dialysis," Seoul, Korea, August 23-25, 1998.
4. "Implementing a firewall for improved patient data security", A Aloui, et al, Presentation at CARS 2000, San Francisco, CA, June 28 - July 1, 2000.

APPENDIX 1

Project Phoenix Diagram



APPENDIX 2

Clinical Operational Protocol for Telemedicine Consultation

This protocol is designed for two cases:

Case 1: The nephrologist is NOT at Union Plaza and he performs a telemedicine round on the patients.

Case 2: The nephrologist is at Union Plaza for his weekly round and he uses the telemedicine system at Union Plaza as a multimedia database.

Case 1: Telemedicine Consultation with the nephrologist NOT at Union Plaza

This type of interaction will occur once a week in addition to the traditional round that is required on a weekly basis by District of Columbia regulations. There are two possibilities here: Either he performs a routine telemedicine consultation or he intervenes when a crisis situation is arising.

I. Telemedicine for Routine Dialysis Rounds:

The nephrologist will perform one telemedicine session per week for each shift of each group of patients (Monday, Wednesday, Friday shifts and Tuesday, Thursday, Saturday shifts) at TRC.

Scheduling the Telemedicine Rounds

The nephrologist informs the nurse on a weekly basis when he is going to do his additional telemedicine round for patients at TRC. This will depend of course on their shift and time but also specifically when he made his physical visit to the site.

For routine dialysis telemedicine, the patients will be “seen” by the nephrologist for approximately ten minutes through the telemedicine system. The nephrologist will have his Consultation Time Sheet ready and marks the beginning and ending of each consultation on it (Figure 2.b).

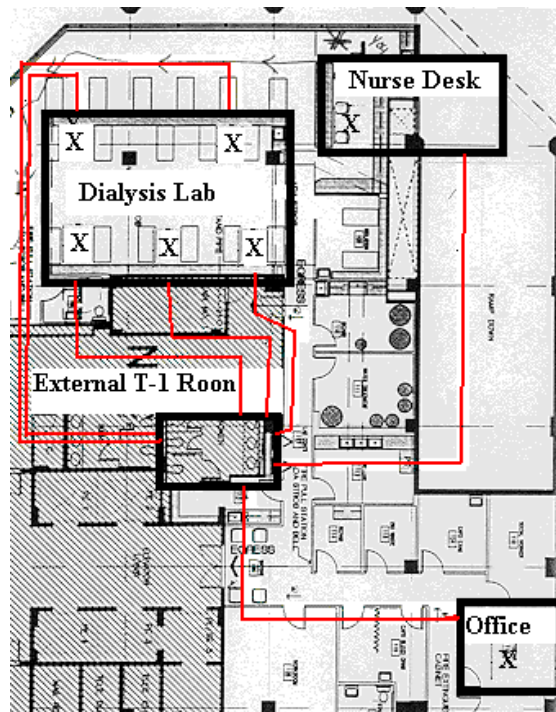


FIGURE 2.a. Physical Layout of Union Plaza Total Renal Care (TRC) Dialysis Unit

Preparation of the Telemedicine System

The system will be locked overnight in the nephrologist's office at TRC Union Plaza. He is the only one who has access to the key. It is wheeled in the patient's location before the first shift on telemedicine day. The concentrator is connected to the buffer PC which is continuously collecting data and located in the patient area as indicated in Figure 2.a. When the telemedicine system is brought to the patient area from the nephrologist's office in the morning then it is immediately connected to the concentrator and prepared to start consultations. The nurse determines via phone where the nephrologist is (home or office) and makes sure that the patch in switch room is connected to the appropriate location. The connection is then established and the consultations can then begin. The telemedicine system is wheeled next to the first patient according to the schedule.

Updating Databases and Storage

Currently the system is based on Windows 3.11 for Workgroups which does not allow for simultaneous updates of databases. In the case of the clinical operational protocol, this implies that all three databases have to be updated to reflect the same data. However, the patient's site (Union Plaza) is the site that will contain the most recent data. Before, each session, the nephrologist will ask the nurse to send him the most recent folders of that day's patients. Once a week, the nephrologist decides which portion of the auscultatory findings for cardiac and pulmonary assessment, fistula still images and dialysis parameters to keep in the patient folder and which to discard. The data that is kept is then transferred to a zip or jazz drive belonging to that patient and containing their information for up to three months. This data also includes all other patient information available in the patient chart such as EKG and Xray reports, lab values etc.

Content of the Routine Telemedicine Consultation

At the beginning of the consultation, the nephrologist greets the patient and discusses general issues with the patient the same way he would when he is performing a physical round. If the patient wishes to discuss personal matters with the nephrologist then headsets with built-in microphones are provided to the patient.

Once this is done, the nephrologist will:

- û ask the nurse about the patient's condition (including blood pressure, temperature, pulse rate, complaints, recent responses to dialysis, etc). If necessary, the nurse can use the headsets as well.
- û perform remote stethoscope evaluation of the patient lungs, heart and fistula. The nurse will then store each of those values in the patient folder.
- û focus on the fistula of the patient and take a snapshot of it. Then he will transfer it to the nurse for storage in the patient's folder on the patient's site at baseline if necessary and if problems arise.
- û if the nurse has any questions about access, the nephrologist can then answer the question via an interactive session and write any recommendations on the image itself and store it the patient folder on the patient's site.
- û the nurse will then take a snapshot of the patient's most recent dialysis parameters (up to the last five minutes), stores them in the patient folder and transmit them to the nephrologist.

II. Telemedicine for Crisis Situations

Crisis situation for telemedicine are defined as follows:

- A patient deciding to stop their dialysis early
- A patient having trouble with vascular access
- Other problems / complications (dyspnea, tachycardia, pyrexia, bleeding, etc) that the nurse may deem necessary to call the nephrologist

If the crisis situation occurs while the nephrologist is performing routine telemedicine rounds with that patient then the nephrologist and the nurse decide what the best course of action is.

If the crisis situation occurs while the nephrologist is performing routine telemedicine rounds on another patient then the crisis situation takes precedence over the routine telemedicine. The session with that patient is interrupted and the system is wheeled next to the patient undergoing the crisis. The nephrologist can then perform a telemedicine consultation with that patient and deal with the situation.

If the crisis situation occurs while the nephrologist is away from the Union Plaza Telemedicine Site then the nurse tries to contact him by phone to his home or office. Depending on his location, the nurse will (if necessary) change the patch of the T1 lines in the switch to the appropriate location (home or office). This is explained in detail in the technical operational manual.

If the patient is deciding to cut short their dialysis session then the nephrologist will intervene and try to convince the patient to continue on dialysis by:

- discussing the implications and health risks of their action
- discussing their specific case and Kt/V values and comparing them to other patients in the unit as well as in other TRC units nationally

If the patient is having vascular access problems then the nephrologist will:

- coach the nurse by providing other options for access, alternative puncturing sites and monitoring through video camera
- help the nurse with whether it is required to send the patient to the ER, doctor's office or not
- monitor the progress of the fistula by comparing stored fistula images to the current situation
- offer to the nurse and patient prophylactic measures to prevent this in the future (ie: heparinization, urokinase, anticoagulant, or angioplasty)

If the patient is having other complications and it is necessary to get in contact with the nephrologist then the nurse will first call the nephrologist to try to resolve the problem via phone. The nephrologist and the nurse will then decide whether it is necessary to establish a telemedicine consult.

During the process the nurse will record all of the above interactions on the form below (Figure 2.b)

Case 2: The nephrologist is at Union Plaza

In this case, the same set up and preparation procedure will be followed as in Case 1.

Routine Consultation:

The nephrologist will perform his rounds as he traditionally does. He will only use the telemedicine system to store patient values in their respective folders. This is done for:

- Storage of heart, lung and fistula audio values via the electronic stethoscope when required for abnormal cases
- Storage of fistula still images in the patient folder.
- Monitoring and storage of dialysis parameters in the patient folder.

He will also pull up patient historical information stored in their folders to compare it with current values.

Crisis Situations:

Crisis situations as defined in Case 1 will not be applicable since the nephrologist will be on-site.

IMPORTANT: Please note that this protocol only applies to patients at Union Plaza who have consented to participate in the study. Patients who have not signed the consent form cannot have access to telemedicine consultations even in crisis situations.

NON ROUTINE TELEMEDICINE CONSULTATION TIMESHEET

DATE_____

Person Filling Form_____

TIME_____

Dialysis Site_____

PATIENT ID#_____

Crisis Situation relates to :

___ Patient requesting to leave early

___ Patient having vascular access problems

___ Other complications: (Please explain)

Was Dr. Winchester contacted ? ____Yes ____No

Was he reached ? ____Yes ____No

If yes, was he at ____Home ____Office ____Page

Was problem dealt with by: ____Phone ____Telemedicine

How was problem resolved ?

Figure 2.b Non-routine Telemedicine Consultation Timesheet

APPENDIX 3

Quality of Life and Patient Satisfaction Surveys

SocioDemographics
KDQoL & Satisfaction with Care
EuroQoL
Satisfaction with Life
Satisfaction with Telemedicine

SOCIODEMOGRAPHIC FORM

Patient ID _____

Date: _____
MM / DD / YY

Site Number ____

I would like to begin by asking you a few questions.

1. What is your gender?

Male..... 1

Female..... 2

2. What category best describes your racial/ethnic background?

(READ CHOICES)

1

2

3

Black (non-Hispanic).....

White (non-Hispanic)..... 4

Hispanic (Puerto Rican, Cuban, Mexican, Chicano, Other Latin 5

American, or Other Spanish).....

Aleut, Eskimo or American Indian.....

Asian/Pacific Islander.....

3. What is your current marital status (READ CHOICES)

1

Married..... 2

Divorced..... 3

Separated..... 4

Widowed..... 5

Single (never married).....

4. What is the highest level of education you have completed? 1

Elementary School..... 2

Some high school or less..... 3

High school diploma or GED..... 4

Vocational School or some college..... 5

College degree..... 6

Some graduate training..... 7

Professional or graduate degree.....

Sociodemographic form
Patient ID _____
Date: _____
MM / DD / YY
Site Number ____

5. What was your annual household income category in 1996 pre-tax dollars from the list. I do not need to know the exact amount. (Please include income from **employment, retirement plans, social security**, and/or **social services**.) (READ CHOICES)

| | |
|---------------------------|---|
| Less than \$6,000..... | 1 |
| \$6,000 to \$11,999..... | 2 |
| \$12,000 to \$23,999..... | 3 |
| \$24,000 to \$35,999..... | 4 |
| \$36,000 to \$47,999..... | 5 |
| \$48,000 to \$74,999..... | 6 |
| \$75,000 or more..... | 7 |

6. How long is your commute time to this dialysis center? (READ CHOICES)

| | |
|---------------------------------------|---|
| | 1 |
| | 2 |
| Less than 30 minutes..... | 3 |
| | 4 |
| 30 minutes to one hour..... | |
| One Hour to one and a half hours..... | |
| Over One and a half hours..... | |

| | |
|---|---|
| 7. Why did you pick this dialysis center? | 1 |
| It is convenient..... | 2 |
| I like the Staff/Service..... | 3 |
| I always come here..... | 4 |
| My insurance covers it..... | |
| Other (specify)_____ | |

THANK YOU FOR YOUR PARTICIPATION

KIDNEY DISEASE AND QUALITY OF LIFE™

SHORT FORM

(KDQOL-SF™)

VERSION 1.2

Patient Study Number: _____

**RAND
1700 Main Street
Santa Monica, California 90407-2138
(310) 393-0411**

STUDY OF QUALITY OF LIFE FOR PATIENTS ON DIALYSIS

WHAT IS THE PURPOSE OF THE STUDY?

This study is being carried out in cooperation with physicians and their patients. The purpose is to assess the quality of life of patients with kidney disease.

WHAT WILL I BE ASKED TO DO?

For this study, we want you to complete a survey today about your health, how you feel and your background.

CONFIDENTIALITY OF INFORMATION?

We do not ask for your name. Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permit identification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

HOW WILL PARTICIPATION BENEFIT ME?

The information you provide will tell us how you feel about your care and further understanding about the effects of medical care on the health of patients. This information will help to evaluate the care delivered.

DO I HAVE TO TAKE PART?

You do not have to fill out the survey and you can refuse to answer any question. Your decision to participate will not affect your opportunity to receive care.

INSTRUCTIONS FOR FILLING OUT SURVEY

- A. This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.
- B. This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.
- C. Please answer the questions by circling the appropriate number or by filling in the answer as requested.

Example:

During the past four weeks, how much back pain have you had?

(Circle One Number)

| | |
|-----------------|---|
| None | ① |
| Very mild | 2 |
| Mild | 3 |
| Moderate | 4 |
| Severe | 5 |

- D. Several items in the survey ask about the effect of kidney disease on your life. Some items will ask about limitations related to your kidney disease, and some items will ask about your well-being. Some questions may look like others, but each one is different. Please answer every question as honestly as possible. If you are unsure about how to answer a question, please give the best answer you can. This will allow us to have an accurate picture of the different experiences of individuals with kidney disease.

THANK YOU FOR COMPLETING THIS SURVEY

YOUR HEALTH

1. In general, would you say your health is:

(Circle One Number)

- | | |
|-----------------|---|
| Excellent | 1 |
| Very good | 2 |
| Good | 3 |
| Fair | 4 |
| Poor | 5 |

2. **Compared to one year ago**, how would you rate your health in general **now**?

(Circle One Number)

- | | |
|---|---|
| Much better now than one year ago | 1 |
| Somewhat better now than one year ago | 2 |
| About the same as one year ago | 3 |
| Somewhat worse now than one year ago | 4 |
| Much worse now than one year ago | 5 |

3. The following items are about activities you might do during a typical day. **Does your health now limit** you in these activities? If so, how much?

(Circle One Number on Each Line)

| | Yes, Limited <u>a Lot</u> | Yes, Limited <u>a Little</u> | No, Not Limited <u>at All</u> |
|---|---------------------------------|------------------------------------|-------------------------------------|
| a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports .. | 1 | 2 | 3 |
| b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 |
| c. Lifting or carrying groceries | 1 | 2 | 3 |
| d. Climbing several flights of stairs ... | 1 | 2 | 3 |
| e. Climbing one flight of stairs | 1 | 2 | 3 |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 |
| g. Walking more than a mile | 1 | 2 | 3 |
| h. Walking several blocks | 1 | 2 | 3 |
| i. Walking one block | 1 | 2 | 3 |
| j. Bathing or dressing yourself | 1 | 2 | 3 |

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular activities **as a result of your physical health**?

(Circle One Number on Each Line)

| | <u>Yes</u> | <u>No</u> |
|---|------------|-----------|
| a. Cut down the amount of time you spent on work or other activities? | 1 | 2 |
| b. Accomplished less than you would have liked?..... | 1 | 2 |
| c. Were limited in the kind of work or other activities?..... | 1 | 2 |
| d. Had difficulty performing the work or other activities (for example, it took extra effort)? | 1 | 2 |

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

| | <u>Yes</u> | <u>No</u> |
|--|------------|-----------|
| a. Cut down the amount of time you spent on work or other activities? | 1 | 2 |
| b. Accomplished less than you would like? | 1 | 2 |
| c. Didn't do work or other activities as carefully as usual ? | 1 | 2 |

6. During the **past 4 weeks**, to what **extent** have your **physical health or emotional problems** interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

Not at all 1

| | |
|-------------------|---|
| Slightly | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

7. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

| | |
|-------------------|---|
| None | 1 |
| Very mild | 2 |
| Mild | 3 |
| Moderate | 4 |
| Severe | 5 |
| Very severe | 6 |

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

| | |
|--------------------|---|
| Not at all | 1 |
| A little bit | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** . . .

(Circle One Number on Each Line)

| | <u>All of the Time</u> | <u>Most of the Time</u> | <u>A Good Bit of the Time</u> | <u>Some of the Time</u> | <u>A Little of the Time</u> | <u>None of the Time</u> |
|---|--------------------------------|---------------------------------|---------------------------------------|---------------------------------|-------------------------------------|---------------------------------|
| a. Did you feel full of pep? | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Have you been a very nervous person? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Have you felt so down in the dumps that nothing could cheer you up? | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Have you felt calm and peaceful? | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you have a lot of energy? | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Have you felt downhearted and blue? | 1 | 2 | 3 | 4 | 5 | 6 |
| g. Did you feel worn out? | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Have you been a happy person? | 1 | 2 | 3 | 4 | 5 | 6 |
| i. Did you feel tired? | 1 | 2 | 3 | 4 | 5 | 6 |
| 10. During the past 4 weeks , how much of the time have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? | | | | | | |

(Circle One Number)

All of the time 1

| | |
|----------------------------|---|
| Most of the time | 2 |
| Some of the time | 3 |
| A little of the time | 4 |
| None of the time | 5 |

11. Please choose the answer that best describes how **TRUE** or **FALSE** each of the following statements is for you.

(Circle One Number on Each Line)

| | Definitely <u>True</u> | Mostly <u>True</u> | Don't <u>Know</u> | Mostly <u>False</u> | Definitely <u>False</u> |
|---|---------------------------|-----------------------|----------------------|------------------------|----------------------------|
| a. I seem to get sick a little easier than other people | 1 | 2 | 3 | 4 | 5 |
| b. I am as healthy as anybody I know | 1 | 2 | 3 | 4 | 5 |
| c. I expect my health to get worse | 1 | 2 | 3 | 4 | 5 |
| d. My health is excellent | 1 | 2 | 3 | 4 | 5 |

YOUR KIDNEY DISEASE

12. How **TRUE** or **FALSE** is each of the following statements for you?

(Circle One Number on Each Line)

| | Definitely <u>True</u> | Mostly <u>True</u> | Don't <u>Know</u> | Mostly <u>False</u> | Definitely <u>False</u> |
|---|---------------------------|-----------------------|----------------------|------------------------|----------------------------|
| a. My kidney disease interferes too much with my life | 1 | 2 | 3 | 4 | 5 |
| b. Too much of my time is spent dealing with my kidney disease | 1 | 2 | 3 | 4 | 5 |
| c. I feel frustrated dealing with my kidney disease | 1 | 2 | 3 | 4 | 5 |
| d. I feel like a burden on my family | 1 | 2 | 3 | 4 | 5 |

13. These questions are about how you feel and how things have been going during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** . . .

(Circle One Number on Each Line)

| | | | | | |
|-------------------------------|--------------------------------|-------------------------------|-------------------------------------|----------------------------|------------------------------|
| None of the <u>Time</u> | A Little of the <u>Time</u> | Some of the <u>Time</u> | A Good bit of the <u>Time</u> | Most of the <u>Time</u> | All of the <u>Time</u> |
|-------------------------------|--------------------------------|-------------------------------|-------------------------------------|----------------------------|------------------------------|

- | | | | | | | |
|---|---|---|---|---|---|---|
| a. Did you isolate yourself from people around you? | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Did you react slowly to things that were said or done? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Did you act irritable toward those around you? | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Did you have difficulty concentrating or thinking? | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you get along well with other people? | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Did you become confused? | 1 | 2 | 3 | 4 | 5 | 6 |

14. During the **past 4 weeks**, to what extent were you bothered by each of the following?

(Circle One Number on Each Line)

- | | <u>Not
at All
bothered</u> | <u>Somewhat
bothered</u> | <u>Moderately
bothered</u> | <u>Very
Much
bothered</u> | <u>Extremely
bothered</u> |
|-----------------------------------|------------------------------------|------------------------------|--------------------------------|-----------------------------------|-------------------------------|
| a. Soreness in your muscles?..... | 1 | 2 | 3 | 4 | 5 |
| b. Chest pain?..... | 1 | 2 | 3 | 4 | 5 |

| | | | | | |
|---------------------------------------|---|---|---|---|---|
| c. Cramps? | 1 | 2 | 3 | 4 | 5 |
| d. Itchy skin? | 1 | 2 | 3 | 4 | 5 |
| e. Dry skin?..... | 1 | 2 | 3 | 4 | 5 |
| f. Shortness of breath?..... | 1 | 2 | 3 | 4 | 5 |
| g. Faintness or dizziness? | 1 | 2 | 3 | 4 | 5 |
| h. Lack of appetite? | 1 | 2 | 3 | 4 | 5 |
| i. Washed out or drained?..... | 1 | 2 | 3 | 4 | 5 |
| j. Numbness in hands or feet?..... | 1 | 2 | 3 | 4 | 5 |
| k. Nausea or upset stomach? | 1 | 2 | 3 | 4 | 5 |

14. (Continued) During the **past 4 weeks**, to what extent were you bothered by each of the following?

(Circle One Number on Each Line)

| | | | | |
|----------------------------------|-----------------------------|-------------------------------|---------------------------------|------------------------------|
| Not at All <u>bothered</u> | Somewhat <u>bothered</u> | Moderately <u>bothered</u> | Very Much <u>bothered</u> | Extremely <u>bothered</u> |
|----------------------------------|-----------------------------|-------------------------------|---------------------------------|------------------------------|

Hemodialysis Patient only

| | | | | | |
|---------------------------------------|---|---|---|---|---|
| l. Problems with your access site? | 1 | 2 | 3 | 4 | 5 |
|---------------------------------------|---|---|---|---|---|

Peritoneal Dialysis Patient only

| | | | | | |
|---|---|---|---|---|---|
| m. Problems with your catheter site? | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|

EFFECTS OF KIDNEY DISEASE ON YOUR DAILY LIFE

15. Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease **bother** you in each of the following areas?

(Circle One Number on Each Line)

| | Not at All <u>bothered</u> | Somewhat <u>bothered</u> | Moderately <u>bothered</u> | Very Much <u>bothered</u> | Extremely <u>bothered</u> |
|---|----------------------------------|-----------------------------|-------------------------------|------------------------------|------------------------------|
| a. Fluid restriction? | 1 | 2 | 3 | 4 | 5 |
| b. Dietary restriction? | 1 | 2 | 3 | 4 | 5 |
| c. Your ability to work around the house? | 1 | 2 | 3 | 4 | 5 |
| d. Your ability to travel? | 1 | 2 | 3 | 4 | 5 |
| e. Being dependent on doctors and other medical staff? | 1 | 2 | 3 | 4 | 5 |
| f. Stress or worries caused by kidney disease?..... | 1 | 2 | 3 | 4 | 5 |
| g. Your sex life?..... | 1 | 2 | 3 | 4 | 5 |
| h. Your personal appearance? | 1 | 2 | 3 | 4 | 5 |

The next two questions are personal and relate to your sexual activity, but your answers are important in understanding how kidney disease impacts on people's lives.

16. How much of a problem was each of the following in the **past 4 weeks**?

(Circle One Number on Each Line)

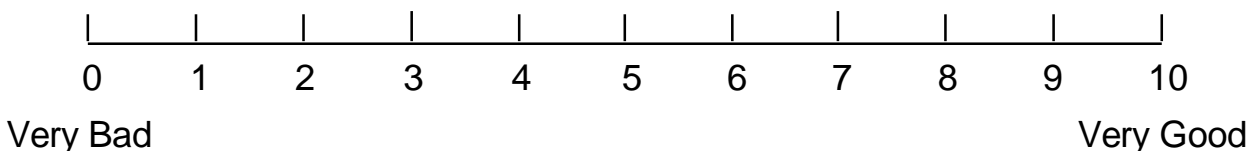
| | <u>Not a Problem</u> | <u>A Little Problem</u> | <u>Somewhat of a Problem</u> | <u>Very Much a Problem</u> | <u>Severe Problem</u> |
|-------------------------------------|----------------------|-------------------------|------------------------------|----------------------------|-----------------------|
| a. Enjoying sex? | 1 | 2 | 3 | 4 | 5 |
| b. Becoming sexually aroused? | 1 | 2 | 3 | 4 | 5 |

For the following question, please rate your sleep using a scale ranging from 0 representing "very bad" to 10 representing "very good."

If you think your sleep is half-way between "very bad" and "very good," please circle 5. If you think your sleep is one level better than 5, circle 6. If you think your sleep is one level worse than 5, circle 4 (and so on).

17. On a scale from **0** to **10**, how would you rate your sleep overall?

(Circle One Number)



18. How often during the **past 4 weeks** did you...

(Circle One Number on Each Line)

| | <u>None of the Time</u> | <u>A Little of the Time</u> | <u>Some of the Time</u> | <u>A Good bit of the Time</u> | <u>Most of the Time</u> | <u>All of the Time</u> |
|---|---------------------------------|-------------------------------------|---------------------------------|---------------------------------------|---------------------------------|--------------------------------|
| a. Awaken during the night and have trouble falling asleep again? | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Get the amount of sleep you need? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Have trouble staying awake during the day? | 1 | 2 | 3 | 4 | 5 | 6 |

19. Concerning your **family and friends**, how satisfied are you with ...

(Circle One Number on Each Line)

| | <u>Very Dissatisfied</u> | <u>Somewhat Dissatisfied</u> | <u>Somewhat Satisfied</u> | <u>Very Satisfied</u> |
|---|------------------------------|----------------------------------|-------------------------------|---------------------------|
| a. The amount of time you are able to spend with your family and friends? | 1 | 2 | 3 | 4 |
| b. The support you receive from your family and friends? | 1 | 2 | 3 | 4 |

20. During the **past 4 weeks**, did you work at a paying job?

(Circle One Number)

Yes 1

No 2

21. Does your health keep you from working at a paying job?

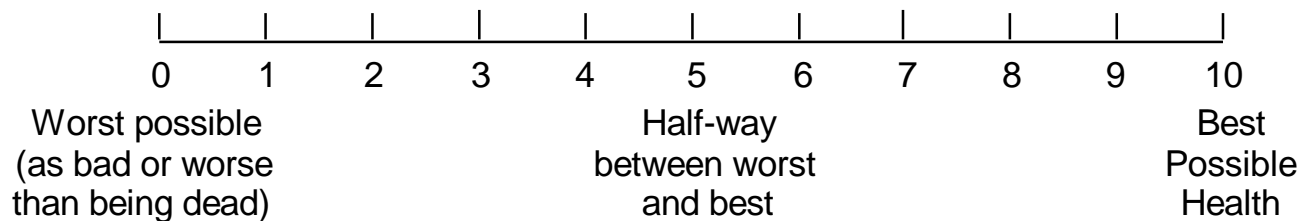
(Circle One Number)

Yes 1

No 2

22. Overall, how would you rate your health?

(Circle One Number)



SATISFACTION WITH CARE

23. Think about the care you receive for kidney dialysis. In terms of your satisfaction, how would you rate the friendliness and interest shown in you as a person?

(Circle One Number)

| | |
|-----------------|---|
| Very Poor | 1 |
| Poor | 2 |
| Fair | 3 |
| Good | 4 |
| Very Good | 5 |
| Excellent | 6 |
| The Best | 7 |

24. How **TRUE** or **FALSE** is each of the following statements?

(Circle One Number on Each Line)

| | Definitely <u>True</u> | Mostly <u>True</u> | Don't <u>Know</u> | Mostly <u>False</u> | Definitely <u>False</u> |
|---|---------------------------|-----------------------|----------------------|------------------------|----------------------------|
| a. Dialysis staff encourage me to be as independent as possible | 1 | 2 | 3 | 4 | 5 |
| b. Dialysis staff support me in coping with my kidney disease | 1 | 2 | 3 | 4 | 5 |

BACKGROUND INFORMATION

25. Do you currently take prescription medications regularly (4 or more days a week) that are prescribed by your doctor for a medical condition? Please don't count over the counter medications like antacids or aspirin.

(Circle One Number)

No..... 1 --->

Please skip to Question 26

Yes 2



25a. How many different prescription medications do you currently take?

Number of Medications: _____

26. How many days total in the **last 6 months** did you stay in any hospital overnight or longer? **(If none, please write in 0)**

Number of Days: _____

27. How many days total in the **last 6 months** did you receive care at a hospital, but came home the same day? **(If none, please write in 0)**

Number of Days: _____

28. What caused your kidney disease?

(Circle All That Apply)

Don't know 1

.....

Hypertension (High Blood Pressure) 2

Diabetes 3

Polycystic Kidney Disease 4

| | |
|----------------------------------|---|
| Chronic Glomerulonephritis | 5 |
| Chronic Pyelonephritis | 6 |
| Other (please specify): _____ | 7 |
| _____ | |

29. When were you born?

| | | | | | | | |
|----------------------|----------------------|---|----------------------|----------------------|---|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | / | <input type="text"/> | <input type="text"/> | / | <input type="text"/> | <input type="text"/> |
| Month | | | Day | | | Year | |

30. What is the highest level of school you have completed?

(Circle One Number)

| | |
|---|---|
| 8th grade or less | 1 |
| Some high school or less | 2 |
| High school diploma or GED..... | 3 |
| Vocational school or some college | 4 |
| College degree | 5 |
| Professional or graduate degree | 6 |

31. What is your gender?

(Circle One Number)

| | |
|--------------|---|
| Male | 1 |
| Female | 2 |

32. How do you describe yourself?

(Circle One Number)

- | | |
|--|---|
| African American or Black | 1 |
| Hispanic or Latino | 2 |
| Native American or American Indian | 3 |
| Asian or Pacific Islander | 4 |
| White | 5 |
| Other (please specify): _____ | 6 |
| _____ | |

33. Are you currently married?

(Circle One Number)

- | | |
|-----------|---|
| No | 1 |
| Yes | 2 |

34. During the **last 30 days**, were you:

(Circle One Number)

- | | |
|--|---|
| Working full-time..... | 1 |
| Working part-time..... | 2 |
| Unemployed, laid off, or looking for work..... | 3 |
| Retired..... | 4 |
| Disabled..... | 5 |
| In school..... | 6 |
| Keeping house..... | 7 |
| None of the above..... | 8 |

35. What kind of health insurance do you have?

(Circle One Number)

- | | |
|---|---|
| None, I have no health insurance | 1 |
| Medicare only | 2 |
| Medicare and any other insurance | 3 |
| Medicaid or Medi-Cal only | 4 |
| Private, fee-for-service health insurance (e.g., Prudential, Aetna, etc.) | 5 |
| HMO, PPO, IPA or other prepaid plan (e.g., Kaiser, Cigna, FHP, etc.) | 6 |
| Other (please specify) _____ | 7 |
| _____ | |

36. What was your total household income (from all sources) before taxes in the **LAST CALENDAR YEAR**, including yourself, your partner, and others you regard as family who live in your household? (Please remember your answers are confidential.)

(Circle One Number)

| | |
|--------------------------|---|
| Less than \$5,000 | 1 |
| \$5,001-\$10,000 | 2 |
| \$10,001-\$20,000 | 3 |
| \$20,001-\$40,000 | 4 |
| \$40,001-\$75,000 | 5 |
| More than \$75,000 | 6 |
| Don't know | 7 |

37. Did someone help you fill out this survey?

(Circle One Number)

| | |
|--|---|
| Yes, a physician or other health care provider | 1 |
| Yes, a family member or friend | 2 |
| Yes, someone else | 3 |
| No | 4 |

38. What is today's date?

| | | | | | | | |
|----------------------|----------------------|---|----------------------|----------------------|---|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | / | <input type="text"/> | <input type="text"/> | / | <input type="text"/> | <input type="text"/> |
| Month | | | Day | | | Year | |

THANK YOU FOR TAKING PART IN THIS STUDY.

| |
|---------|
| EUROQOL |
|---------|

Patient ID _____

Date: _____
MM / DD / YY

Site Number ____

In the next section, we are interested about your personal view. Listen and pick the statement that describes you own health state today.

Group1

- | | |
|--|---|
| I have no problems in walking about..... | 0 |
| I have some problems in walking about..... | 1 |
| I am confined to bed..... | 2 |

Group 2

- | | |
|--|---|
| I have no problems with self care..... | 0 |
| I am having some problems with washing and dressing..... | 1 |
| I am unable to wash or dress myself..... | 2 |

Group 3

- | | |
|--|---|
| I have no problems performing my usual activities (e.g. work, study, housework, family or leisure activities) | 0 |
| I have some problems performing usual activities..... | 1 |
| I am unable to perform my usual activities..... | 2 |

Group 4

- | | |
|--|---|
| I have no pain or discomfort..... | 0 |
| I have moderate pain pain or discomfort..... | 1 |
| I have extreme pain or discomfort..... | 2 |

Group 5

- | | |
|---|---|
| I am not anxious or depressed..... | 0 |
| I am moderately anxious or depressed..... | 1 |
| I am extremely anxious and depressed..... | 2 |

To help you say how good or bad your health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100, and the worst state you can imagine by 0.

We would like you to indicate on this scale how good or bad is your own health today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your current health state is.

| | | |
|--|--|---|
| <div style="border: 1px solid black; padding: 10px; text-align: center;"> Your own health state today </div> | BEST IMAGINABLE HEALTH STATE | ----- 100 |
| | | ----- 95 ----- 90 ----- 85 ----- 80 ----- 75 ----- 70 ----- 65 ----- 60 ----- 55 ----- 50 ----- 45 ----- 40 ----- 35 ----- 30 ----- 25 ----- 20 ----- 15 ----- 10 ----- 5 |
| | WORST IMAGINABLE HEALTH STATE | ----- 0 |

| |
|-------------------------------------|
| Satisfaction with Life Scale |
|-------------------------------------|

Patient ID _____

Date: _____

MM / DD / YY

Site Number ____

I will read five statements to you. Indicate on a scale of 1 to 7 the extent to which you disagree or agree. (1 is strongly disagree, 7 is strongly agree.)

1. In most ways, my life is close to ideal.

| | | | | | | |
|----------------------|----------|----------------------|---------|-------------------|--------|-------------------|
| 1..... | 2..... | 3..... | 4..... | 5..... | 6..... | 7 |
| Strongly Disagree | Disagree | Slightly Disagree | Neither | Slightly Agree | Agree | Strongly Agree |

2. The conditions of my life are excellent.

| | | | | | | |
|----------------------|----------|----------------------|---------|-------------------|--------|-------------------|
| 1..... | 2..... | 3..... | 4..... | 5..... | 6..... | 7 |
| Strongly Disagree | Disagree | Slightly Disagree | Neither | Slightly Agree | Agree | Strongly Agree |

3. I am satisfied with my life.

| | | | | | | |
|----------------------|----------|----------------------|---------|-------------------|--------|-------------------|
| 1..... | 2..... | 3..... | 4..... | 5..... | 6..... | 7 |
| Strongly Disagree | Disagree | Slightly Disagree | Neither | Slightly Agree | Agree | Strongly Agree |

4. So far, I have gotten the important things I want in life.

| | | | | | | |
|----------------------|----------|----------------------|---------|-------------------|--------|-------------------|
| 1..... | 2..... | 3..... | 4..... | 5..... | 6..... | 7 |
| Strongly Disagree | Disagree | Slightly Disagree | Neither | Slightly Agree | Agree | Strongly Agree |

5. If I could live my life over, I would change almost nothing.

| | | | | | | |
|----------------------|----------|----------------------|---------|-------------------|--------|-------------------|
| 1..... | 2..... | 3..... | 4..... | 5..... | 6..... | 7 |
| Strongly Disagree | Disagree | Slightly Disagree | Neither | Slightly Agree | Agree | Strongly Agree |

| |
|---|
| Patient Satisfaction with Telemedicine |
|---|

Control group: skip to question 5.

Patient ID _____

Date: _____

MM / DD / YY

Site Number __ __

Telemedicine is live, electronic, interactive audiovisual communications between physician and patient. Its goal is to improve medical care delivery. I will read some statements tell me if you agree or disagree. (READ Statements and CHOICES)

| | YES | NO |
|---|-----|----|
| 1. Do you think that you would have received better treatment if the physician was at the center? | 1 | 0 |
| 2. What are the advantages of this kind of examination? | 1 | 0 |
| a. Waiting time to talk to the doctor was reduced | 1 | 0 |
| b. Health care expense was reduced | 1 | 0 |
| c. New technology was exciting | 1 | 0 |
| d. Examination was more thorough | 1 | 0 |
| e. I was able to observe the examination on the screen | 1 | 0 |
| f. I was able to talk to the doctor directly | 1 | 0 |
| g. The doctor had all the information s/he needed to help me out. | 1 | 0 |
| h. Other | 1 | 0 |
| 3. What are the disadvantages of this kind of examination? | 1 | 0 |
| a. I did not have a proper dialogue with the doctor. | 1 | 0 |
| b. I was not sure that the doctor really understood my problem | 1 | 0 |
| c. I was not sure the examination was thorough enough | 1 | 0 |
| d. I feel uncomfortable appearing on video | 1 | 0 |
| e. I feel lack of personal contact with the doctor | 1 | 0 |
| f. I could not see the doctor very clearly | 1 | 0 |
| g. I could not hear the doctor very clearly | 1 | 0 |
| h. Other | 1 | 0 |
| 5. Which alternative would you select for a future consultation with a specialist? (READ CHOICES) | 1 | 0 |
| a. Only in-person consultation | 1 | 0 |
| b. One in-person visit, and teleconference for follow-up | 1 | 0 |
| c. Only teleconference | 1 | 0 |
| d. I don't care | 1 | 0 |

Satisfaction with Telemedicine**Patient ID** _____**Date:** _____**MM / DD / YY****Site Number** __ __

Please indicate how do you feel about the following statements. 1 is strongly disagree and 5 is strongly agree. (READ CHOICES)

| | Strongly Disagree | Slightly Disagree | Neutral | Slightly Agree | Strongly Agree |
|---|----------------------|----------------------|---------|-------------------|-------------------|
| 4. All things considered, how did you feel about being examined by a specialist who was not present in the room? | 1 | 2 | 3 | 4 | 5 |
| 5. I could talk with the Doctor using Telemedicine as well as I could talk with him or her in person. | 1 | 2 | 3 | 4 | 5 |
| 6. It is harder to ask the doctor questions using Telemedicine than it is in person. | 1 | 2 | 3 | 4 | 5 |
| 7. It is harder to understand the doctor using Telemedicine than it is in person. | 1 | 2 | 3 | 4 | 5 |
| 8. I would rather see my doctor using Telemedicine now than have to wait a week to see him in person. | 1 | 2 | 3 | 4 | 5 |
| 9. I would rather see my doctor using Telemedicine now than have to wait a few days to see him or her in person. | 1 | 2 | 3 | 4 | 5 |
| 10. I think the doctor was able to get a good idea about my medical problem by using Telemedicine as s/he would have gotten had I seen him today. | 1 | 2 | 3 | 4 | 5 |
| 11. I did not feel I can say everything I want to say to the doctor because I do not feel that I could keep my discussion private. | 1 | 2 | 3 | 4 | 5 |
| 12. I do not mind using Telemedicine | 1 | 2 | 3 | 4 | 5 |
| 13. I would not mind using only the Telemedicine system as long as I can talk to the doctor. | 1 | 2 | 3 | 4 | 5 |

APPENDIX 4

Interview Guide for Patients

- 1) Describe your first impressions/experience with the system. How have they changed? Is it different than you thought it would be?
- 2) What do you think of the telemedicine system?
- 3) How does it compare with seeing the doctor in person?
- 4) What do you like? What don't you like?
- 5) Do you feel comfortable talking with Dr. Winchester using the system?
- 2) When do you think telemedicine is most useful?
- 3) Are there ever situations when you would rather see the doctor in person? Which ones?
- 4) How does Dr. Winchester use the system to communicate with you effectively?
- 5) Are there any ways that he could become more effective?
- 6) Have you told other people about your telemedicine experience? What do you say about it?
- 7) Do you think that telemedicine is an important tool for hemodialysis patients? Why?
- 8) How could we make the system better?
- 9) Anything you would like to add?

APPENDIX 5

HCU Form

Patient ID _____

Date: _____
MM / DD / YY

Site Number ____

HEALTH CARE UTILIZATION FORM

- 1. Were you hospitalized at all this past week? (To be hospitalized a patient must be kept overnight in a hospital).**

Yes.....1

No.....0

If so, at what hospital? _____

What day(s) this past week were you hospitalized? (CIRCLE ALL THAT APPLY)

MON TUE WED THUR FRI SAT SUN

- 2. Were you treated at an emergency room this past week?**

Yes.....1

No.....0

If so, at what hospital and for how long? _____

What day(s) this past week were you treated in the Emergency Room? (CIRCLE ALL THAT APPLY)

MON TUE WED THUR FRI SAT SUN

- 3. Did you visit your personal physician this past week?**

Yes.....1

No.....0

- 4. Did you receive a home health care visit this past week?**

Yes.....1

No.....0

How long was the visit? _____

What day(s) this past week were you visited by a home health care provider? (CIRCLE ALL THAT APPLY)

MON TUE WED THUR FRI SAT SUN

5. Did you use any new medical equipment, like a wheelchair, walker, or cane, this past week?

Yes.....1

No.....0

If so, what was it? _____

Did you purchase, rent or borrow this item? ☐ PURCHASE ☐ RENT ☐ BORROW

Do you know the price of the item? \$_____

APPENDIX 6

Home Peritoneal Dialysis Baseline Questionnaire

History of Managing Illness and Threrapy

1. When and how did you first notice you were becoming ill?
2. How were you diagnosed?
3. What kinds of therapy did you initially try?
 - a. Did you ever attempt HPD?
 - b. If so, please tell us about your experiences
 - c. Did you try therapies recommended by someone other than your doctor?
4. What kinds of work did you/your spouse/other family members have to do to manage your illness and therapy?
 - a. How did you decide who would do what tasks?
 - b. Have you changed who is responsible for the various tasks since then?
 - c. How did this work affect your spouse/your family members?
 - d. Has this caused conflict in your household?
5. How have the illness and associated work affected your ability to hold a job and develop your career?
 - a. Did you lose or have to change jobs as a result of your illness?
 - b. If so, what did you do to find new work?
 - c. If you are unemployed, how are you supporting yourself?
6. How have the illness and associated work affected your life at home?
 - a. Did you have to change how you and your family performed house chores such as cleaning and cooking?
 - b. How has this experience affected the feelings your family members have for you and each other?

7. How has being ill changed your hopes for yourself?

Expectations for Home Peritoneal Dialysis (HPD)

1. What concerns do you have about HPD?
 - a. What do you think about the possibility of infection?
 - b. Do you think the telemedicine might help you?
 - c. Do you think you can manage the system?
2. What hopes do you have for HPD?
3. Do you think this will change the work you must do to manage your illness?
 - a. If so, how do you think the work will change?
 - b. Will it change who has to do the work to manage your illness?
4. Do you think this will change your ability to perform your job or your job opportunities?
 - a. If so, how do you expect it to change?
 - b. Do you expect to work more or less easily?
 - c. Do you expect to be able to acquire or return to a better job?
5. Do you expect this to change life around your household?
 - a. For example, do you expect this to change responsibility for doing housework and how?
 - b. How will you arrange any changes you and you family might make?
6. Do you think HPD will lessen or heighten conflict in your home concerning your illness?
7. Do you think HPD will enhance opportunities for your life?

APPENDIX 7

Home Peritoneal Dialysis Follow-Up Questionnaire

I. Work Related to HPD

1. I am going to ask you some questions to help me understand how comfortable you are with the home dialysis you are currently using.
 - a. Please tell me the most serious problem you have had, if any, setting up your dialysis equipment.
 - b. Please tell me the most serious problem you have had, if any, operating your dialysis equipment.
 - c. Did the home dialysis training you received prepare you to resolve problems setting up your dialysis equipment?
 - d. Did the home dialysis training you received prepare you to resolve problems operating your dialysis equipment?
 - e. Considering both setting up and operating your dialysis equipment, have you made adjustments to using the dialysis equipment that are different from what you were taught?
 - f. In spite of training and adjustments you might have made, sometimes-unexpected things can happen. Have you experienced any unexpected events or mishaps with your dialysis equipment?
2. Now I am going to ask you some questions about telemedicine and your home dialysis treatment.
 - a. Has working with a nurse by telemedicine helped you in operating your dialysis equipment?

{ IF 2a is “Yes” ASK 2b; OTHERWISE GO TO 2c }

- b. What specific things has the nurse helped you with?

- c. Do you think that you still need to consult with the nurse regularly on how to use the HPD equipment?
- d. Compared normal dialysis treatment, has telemedicine added new tasks to your care that you would prefer not to do?

{ IF 2d is “Yes” ASK 2e; OTHERWISE GO TO 2f }

- e. Please tell me about the new task that you would most prefer not to do.
- f. Compared normal dialysis treatment, has telemedicine added new burdens to your care that you would prefer not to deal with?

{ IF 2f is “Yes” ASK 2g; OTHERWISE GO TO 2h }

- g. Please tell me about the greatest burden that you would most prefer not to deal with.
- h. Do you think that you can manage all the tasks associated with telemedicine supported HPD or are they too much work?
- i. If telemedicine were not available to help you with your dialysis treatment, would this be a burden for you?

{ IF 2i is “Yes” ASK 2j; OTHERWISE GO TO QUESTION 3 }

- j. Please tell me what your greatest burden would be if telemedicine were unavailable to you.
3. Home dialysis with telemedicine support is different from regular dialysis treatment and may involve differences in how you and your family manage your treatment. Now, I am going to ask you some questions about how you and your family manage your treatment.

- a. Do other family members help you manage the tasks related to your dialysis treatment and telemedicine support?

{ IF 3a is “Yes” ASK 3b; OTHERWISE GO TO SECTION II, QUESTION 4 }

- b. Has your dialysis treatment created new tasks for your family that they did not anticipate?

{ IF 3b is “Yes” ASK 3c; OTHERWISE GO TO SECTION II, QUESTION 4 }

- c. Please tell me about the most important of these new family tasks.
- d. How did you decide who would do what tasks?
- e. Have performing these new tasks created conflicts in your family?
- f. If so, how are you managing them?
- g. Do you think your family can manage all these tasks or are they too much work?

II. Consequences of HPD for Everyday Life

4. Now I am going to ask you some questions about how home dialysis and telemedicine have affected the everyday life of you and your family.

- a. Has home dialysis and telemedicine affected your everyday life in any way, positively or negatively. For example, has your dialysis treatment given you more time to pursue other activities?

{ IF 4a is “Yes” ASK 4b; OTHERWISE GO TO SECTION III, QUESTION 5 }

- b. Has home dialysis created changes in your daily schedule compared to before you started this treatment?

DO YOU WANT A FOLLOW-UP HERE (e.g. “How has your schedule changed?”)

- c. Has home dialysis changed how you and your family perform house chores such as cleaning and cooking?

{ IF 4c is “Yes” ASK 4d; OTHERWISE GO TO QUESTION 4e }

- d. Please tell me about the most important changes you and your family have made concerning household chores.

- e. Telemedicine and home dialysis may affect your ability to manage your everyday schedule of activities. Has telemedicine helped you manage your daily activities or has it made managing your daily activities more difficult?

{ IF 4e is “Yes” ASK 4f; OTHERWISE GO TO QUESTION 4g }

- f. How has telemedicine HELPED/HURT your ability manage your daily activities?"

- g. Telemedicine and home dialysis might affect your ability to work and manage your career. Has telemedicine helped or hurt you in your work life?

{ IF 4g is “Yes” ASK 4h; OTHERWISE GO TO SECTION III, QUESTION 5 }

- h. Please tell me how telemedicine has HELPED/HURT you in your work life.

APPENDIX 8

The CPRI Toolkit: Managing Information Security in Health Care

Introduction

Computer-based patient record systems (CPRS) may potentially achieve greater protection of health information than paper-based records. Ensuring an appropriate and consistent level of information security for computer-based patient records, both within individual health care organizations and throughout the entire health care delivery system, requires organizations entrusted with health care information to establish formal information security programs. Recognizing the importance of information security in managing computer-based patient records, the Computer-based Patient Record Institute (CPRI) chartered the Work Group on Confidentiality, Privacy, and Security to promote this process. Since its inauguration in 1993, the Work Group has developed and published a series of topical guidelines on improving information security for organizations implementing CPRS.

The guideline series addresses individual issues in information security, but, taken as a whole, promotes a comprehensive organizational process. The CPRI believes that managing health care information requires integrating good security processes into the everyday working routines of all staff, not just implementing security measures. Toward that end, the CPRI created a new Task Force to consolidate its guideline series into a toolkit that outlines general principles and provides “best practice” examples of how health care providers should manage the security of their paper and electronic records. The sections of the *CPRI Toolkit* identify key activities that health care providers should initiate as part of managing information security, including:

- **Monitoring and adjusting to the changing laws, regulations, and standards**
- **Developing, implementing, and continuously updating data security policies, procedures, and practices**
- **Enhancing patient understanding of the organization’s information security efforts**
- **Institutionalizing responsibility for information security**

Each section includes an introduction, a copy of the latest edition of the pertinent CPRI guideline, several case studies with sample policies, procedures and forms, and extensive references to print and Internet sources of more information. A consolidated annotated bibliography, a list of Web sites, and a glossary of terms appear at the end of the *CPRI Toolkit*. With this toolkit, any health care provider should be able to plan, implement, and evaluate a

security surveillance process scaled to their organizational needs. These resources should aid healthcare organizations in securely managing information, particularly as they develop responses to new federal regulations and laws such as HIPAA.

Monitoring Changing Laws, Regulations, and Standards

Currently, questions of health information security and medical privacy are of utmost importance in the United States. Hardly a day goes by that *The Washington Post*, *The New York Times*, or *USA Today* do not feature an article about some aspect of medical privacy. Opinion polls document that the American public regards the data management practices of most large organizations with great skepticism. In partial response to these and other expressions of public concern, President Clinton commissioned a task force on medical privacy as part of his health care reform efforts. Although the recommendations of the privacy task force died along with Clinton's plan, federal legislators have incorporated some of their intent, particularly the requirement of federal medical privacy legislation, into subsequent approaches to health care reform. . The Health Insurance Portability and Accountability Act of 1996 (HIPAA) creates specific requirements for the Congress and the Department of Health and Human Services (DHHS). Because of HIPAA, the legal and regulatory environment for managing patient medical records has dramatically changed. DHHA has developed regulations for managing health information security (see below Chapter Three). Efforts to develop federal medical privacy requirements continue in both Congress and DHHS. DHHS led the way on medical privacy by designing model rules to guide Congress and/or its own process of rulemaking if necessary. Meanwhile, many standards-setting organizations are busy addressing the problems of medical privacy and the security of health care information from their own perspectives. The *CPRI Toolkit* contains summaries of the DHHS rules, the DHHS model medical privacy provisions, information about tracking state laws on medical privacy, and a thorough explanation of the standards-setting process in medical informatics. As an example of how two important standards-setting organizations in health care, the Joint Commission on the Accreditation of Healthcare Organizations and the National Committee on Quality Assurance, are beginning to incorporate demands for adequate data security practices into their evaluation criteria, a copy of the Executive Summary of *Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment* can be found in chapter three of the *CPRI Toolkit*.

Developing Policies, Procedures, and Practices for Information Security

Changes in the regulatory and legal environments, the security risks of distributed networks and systems, ever-changing information technology, and rising patient expectations all require health care organizations to continuously update their data security policies, procedures, and practices. A security team must take primary responsibility for coordinating this effort through careful risk analysis, security policy review, and technical and operational enhancements. The security team's efforts will fail, however, without strong business and clinical leadership from throughout the organization. Even if key leaders accept responsibility for maintaining the confidentiality of patient identifiable information, staff will probably resist taking on new tasks that further complicate their work and compete with current tasks. The security team must recognize that enhancing the organization's security capability requires transforming institutional resistance into a mission-based mobilized security effort. A security team that neglects building support for its efforts risks failure.

Included in the *CPRI Toolkit* are sample documents illustrating approaches to security policies, security risk analyses, patient consent and disclosure documents, and other issues from several organizations including the American Health Information and Management Association, Kaiser Permanente of Northern California, Partner HealthCare System, Inc., Harvard Vanguard Medical Associates, and several NLM-funded sites. These examples should assist any health care program, large or small, in its efforts to enhance the security of its confidential information.

Enhancing Patient Understanding of Information Security Efforts

As the DHHS recommendations on confidentiality make clear, health care providers face new obligations in informing patients about how they manage health information. The DHHS recommendations signal some broad social changes, however, whose significance transcends the narrow legal and regulatory context of their development. Reforms in health care finance (specifically the emergence of managed care) are refocusing some aspects of health care from the doctor-patient relationship to the organization-patient relationship, thus making health care organizations accountable to patients in new ways. In addition to being accountable for health care processes and outcomes, organizations are becoming accountable to patients for their business practices, particularly for what they do with information about their individual cases. These changes, as well as DHHS proposals, will increasingly require health care organizations to obtain new types of consent, provide patients access to information historically reserved for institutional use only, educate patients about their business practices, and extend new services to their patients using electronic media. Patients are also demanding a variety of Internet and web-

based healthcare services, including email and access to their medical records. Model examples for how some health care organizations are trying to meet these new obligations are included in the *CPRI Toolkit*.

Institutionalizing Responsibility for Information Security

The well known maxim “Confidentiality is everybody’s business” states the basic truth.

Transforming this truism into practice requires institutional work and personal commitment. This toolkit provides models and methods for assisting health care providers to manage patient records as a broad institutional process, including the technical protection of the information system. In addition to these concrete methods, however, health care providers should institutionalize a sense of responsibility for maintaining patient confidentiality at all levels, including individual staff, program managers, and organizational administrators. Health care providers should develop methods for binding these levels of responsibility together such as in the illustration of the “Trustee/Custodian Agreements” from Kaiser Permanente explained in the final section of the *CPRI Toolkit*. By creating the trustee/custodian relationship, Kaiser has institutionalized mutual responsibility for secure information control between clinical and information staff, thus integrating it not segregating it from everyday work. Not all health care providers require developing an arrangement as formal as Kaiser’s Trustee/Custodian Agreement. Yet, most organizations larger than a single physician office differentiate between clinical and information systems staff. Formulating roles institutionalizing a sense of mutual responsibility for information security among staff operationalizes the idea that confidentiality is everybody’s business. Instead of relegating information security to the domain of the technical specialists and parceling responsibility for managing patients only to clinicians, all staff assumes responsibility for the enterprise, its patients, and the confidentiality of their information.

APPENDIX 9
Sample Agenda

**Privacy, Security & Confidentiality
of Medical Records 2000:**
Complying With New HIPAA Requirements©

A Production of Nonprofit Management Inc., and Health Tech Strategies, LLC

Sponsored by:

**American Hospital Association * Computer-based Patient Record Institute * 3Com Healthcare
Health Information Privacy Alert * IBM Global Healthcare * Presideo * Johnson & Johnson Inc.
McKenna & Cuneo, LLP * MedicalLogic * The Center For Health Affairs * US West
Communications**

**Friday, May 12, 2000
University of Minnesota
The Humphrey Institute Conference Center
301 19th Avenue South
Minneapolis, MN**

**In Collaboration With:
Minnesota Medical Association
Minnesota Organization of Leaders in Nursing**

| | | |
|---|----------------------------|--|
| 7:30 | | Registration & Continental Breakfast |
| Introduction | | |
| 8:30 | Welcome | Keith Krueger, President, Nonprofit Management, Inc. |
| 8:45 | Overview & Objectives | Jeff Collmann, Ph.D., Georgetown University Medical Center & Editor of <i>CPRI Toolkit: Managing Information Security in Healthcare</i> and Workshop Moderator |
| Laws, Rules, and Regulations | | |
| The Health Insurance Portability and Accountability Act of 1996 (HIPAA) | | |
| 9:00 | Overview of Proposed Rules | Dr. Collmann |
| 9:30 | Organizing for HIPAA: | |

| | | |
|---|---|--|
| Steps Toward Compliance Healthcare | | Lisa Kreeger, IBM Global |
| 10:15 | Coffee Break | |
| 10:30 | Congressional & State Outlook | Keith Krueger , President, NonProfit Management, Inc., |
| 11:00 | Medical Privacy: Business Issues Contracts & Liability | Alex Brittin, J.D. Partner McKenna & Cuneo, LLP |
| Lunch and Special Presentation | | |
| 12:00 | Buffet set-up outside the room | |
| 12:30 | Keynote Address | Michael J. Ackerman, Ph.D., Asst. Director National Library of Medicine |
| Updating Policies, Practices, and Procedures | | |
| 1:15 | | John Conard, Application Sales Engineer (ASE), US WEST |
| 1:45 | HIPAA Risk Assessment | Christopher Alberts, Software Engineering Institute Carnegie Mellon University |
| 2:30 | Global Considerations | Kent Mottle, J.D., Corporate Office of Research Johnson & Johnson |
| 3:00 | Biometrics | Mariann Yeager, Director, Industry Relations, Presideo, Inc. <i>Securing Medical Records Biometrically</i> |
| 3:45 | Break | |
| Enhancing Patient Understanding | | |
| 4:00 | Consent, Disclosure, and Inspection | Dr. Collmann |
| | Educating Patients About Security | |
| Institutionalizing Security Responsibility | | |
| 4:30 | How to use the <i>CPRI Toolkit</i> | Dr. Collmann |